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Calendar No. 874

99th Congress
2d Session

SENATE

Report
99–424

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AMENDMENTS OF 1986

REPORT

OF THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

together with

ADDITIONAL VIEWS

TO ACCOMPANY

S. 2792

September 3, 1986.—Ordered to be printed

Filed under authority of the order of the Senate of August 16 (legislative day, August 11), 1986

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Mr. Helms, from the Committee on Agriculture, Nutrition, and Forestry, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 2792]

The Committee on Agriculture, Nutrition, and Forestry reports an original bill (S. 2792) to amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes, and recommends the bill do pass.

Summary of Major Provisions

S. 2792, as reported by the Committee, will extend the authorization for appropriations for the pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act for 5 years.

It also will substantially amend the Act to improve the pesticide approval process, strengthen provisions that protect the public, make health data available on pesticides, ensure that farmers and other users of pesticides are treated fairly under the pesticide program, and provide an efficient and equitable regulatory program for producers and distributors of pesticides.

The major provisions of the bill include—

—Provisions for public access to pesticide health and safety data.

—New requirements for conditional pesticide registration.

—A new reregistration program to ensure that pesticides with older registrations are reexamined and found to be safe.

—An expanded program for regulation of inert ingredients in pesticides.

—Provisions to enable State agencies to obtain pesticide data from EPA.

—Improvements to the public interim administrative review process (used to review currently registered pesticides for health and safety risks), and the procedures to be followed if a pesticide registration is to be cancelled or denied.

—Provisions for required changes in pesticide labels under expedited procedures.

—Sanctions for submission of false health or safety data on a pesticide, and procedures to ensure replacement of invalid data.

—Updating of provisions relating to recordkeeping and inspections under the Act.

—Warning and information requirements for exported pesticides.

—Improved procedures for training and certifying applicators of pesticides, including refresher training.

—Requirements for recordkeeping by pesticide dealers and applicators, and access to certain records for employees and customers.

—Required cooperation or cost-sharing in the development of health and safety data on currently registered major agricultural pesticides.

—Revisions of the rules under which the compensation must be paid when an applicant for registration of a pesticide uses another person's data in the pesticide registration process and the establishment of judicial review of such compensation.

—A requirement for the establishment of criteria under which State pesticide registrations for special local needs could be disapproved.

—Provisions to reduce burdensome requests for information under the Act.

—Strengthening of the enforcement and penalty provisions of the Act.

—New procedures for judicial review of the regulation promulgated under the Act, with special provisions for agricultural producers.

—Coordination of action by EPA and the Department of Labor (under OSHA) with respect to pesticide worker safety, and requirements for training and worker protection regulations under the Act.

—A requirement that the Administrator protect drinking water and groundwater against pesticide contamination.

—Establishment of liability rules to protect farmers who use pesticides correctly.

—Restoration of patent term for certain pesticide products.

—Establishment of uniform tolerances for pesticide residues.

Following are brief descriptions of the major provisions of the bill:

DETAILED EXPLANATION

Preregistration access to data: The bill provides for public access to health and safety data submitted to support an application for the registration of a pesticide containing a new active ingredient, or to authorize the initial food use of a pesticide active ingredient. Public access would only be granted for the purpose of allowing public comment on the application. A person seeking access to data supporting an application for registration must affirm that the person is not directly or indirectly, or acting on behalf of someone, in the pesticide business. Criminal penalties would be required for wrongful disclosures of information. (Secs. 101 and 102.)

Conditional registrations: The bill will prohibit conditional registration amendments of a pesticide for additional uses unless the additional use is in the public interest. A conditional amendment to add a use could not be granted if data concerning possible chronic effects have not been submitted, and the registrant has had a reasonable time to submit the data, unless the amendment is to add a minor use. (Sec. 103.)

Reregistration of registered pesticides: The bill will require the Administrator of the Environmental Protection Agency to reregister pesticides with active ingredients contained in pesticides registered before November 1, 1984, with outstanding data requirements. Reregistration would be completed in five phases:

(1) EPA would publish a priority list of the active ingredients contained in pesticides that must be reregistered. Priority would be given to active ingredients that have not already been assigned reregistration requirements, and that are in use on or in food or feed and may result in postharvest residues or residues of potential toxicological concern in potable groundwater, edible fish, or shellfish, have significant outstanding data requirements, or are used where worker exposure is most likely.

(2) Registrants must notify the Administrator whether or not the registrant intends to seek reregistration of a listed pesticide. Registrants must also identify and agree to replace missing and inadequate data for the pesticide.

(3) Registrants must summarize studies previously submitted in support of reregistration, reformat certain data in the studies according to EPA guidelines, and promise to fill outstanding data requirements.

(4) The Administrator must review submissions to determine if all data that are missing or inadequate were identified. Outstanding data requirements for each active ingredient must be published, and four years would be allowed for the submission of required data.

(5) EPA must conduct a thorough examination of all data, and determine if the pesticide is eligible for reregistration. Applicants for reregistration of the pesticide must then supply supplemental product-specific data. The Administrator must make a final decision on reregistration not later than one year after the submission of all required data.

The bill provides for the payment of reregistration fees based on active ingredients. Collectively, registrants of each pesticide registered for a major use on food or feed must pay an initial fee of

$50,000 with the phase two submission. A final fee of $100,000 would be paid under phase three.

Registrants of each pesticide registered for a major use on food or feed for which registration requirements already have been issued, must collectively pay a fee of $100,000 at a time to be determined by the Administrator.

Registrants of each pesticide not registered for a major food or feed use must collectively pay a fee determined by the Administrator (but not greater than $150,000 or less than $75,000). If registration requirements already have been issued for the pesticide, the fee could not be greater than $100,000 or less than $50,000.

Fees could be reduced or waived for minor use pesticides, pesticides for which the value or volume of use is small, antimicrobial active ingredients for which production levels do not exceed 1,000,000 pounds per year, and certain small business registrants. Small business registrants would not be required to pay reregistration fees in excess of 3-year average annual gross revenues from pesticides containing active ingredients as follows: (1) less than $5,000,000, the registrant would pay 0.5 percent of such revenue; (2) $5,000,000 or more but less than $10,000,000, the registrant must pay 1 percent of such revenue; or (3) $10,000,000 or more, the registrant must pay 1.5 percent of the revenue, but not more than $150,000. Fees are to be apportioned, according to domestic market share, among registrants. (Secs. 104 and 105.)

Inert ingredients: The bill will direct the Administrator to establish a priority list of between 50 and 75 ingredients. Listed would be (1) inerts that appear to cause a pesticide to trigger a public interim administrative review; (2) inerts for which additional data are reasonably necessary to assess whether they may cause unreasonable adverse effects, that are similar in molecular structure to chemicals known to cause unreasonable adverse effects, and that have significant use in pesticides or to which there is significant exposure from pesticides; and (3) inerts for which additional data are needed to assess whether they may result in unreasonable adverse effects and to which there is significant exposure from pesticides. Within one year, the Administrator must determine if additional data on a list inert ingredient are needed, and such data must be submitted within four years. Within one year after submission of the data, the Administrator must take appropriate regulatory action.

The bill would require modification of pesticide ingredient statements to show the name of each inert ingredient in a pesticide that the Administrator determines must appear in the statement because of the hazard that may be posed by the use pattern and concentration level of the inert ingredient, and the name of any inert ingredient for which the Administrator has required additional data because it appears to cause a pesticide to trigger a public interim administrative review. (Secs. 106 through 109.)

Public right to know: The bill will require that any producer operating a pesticide production establishment to prepare or obtain a fact sheet, summarizing relevant health, safety, and environmental data for each active ingredient manufactured or used at the establishment. The producer must furnish a copy of the fact sheet to any person on request. Producers must furnish to EPA annual reports that include the name of each ingredient for which a fact sheet is required, the location of the establishment, and a copy of the most current fact sheet. Fact sheets and annual reports must be made available to the public. (Sec. 201.)

Data disclosure to states: The bill will require the Administrator to disclose to a State data or information acquired under the Act if the State provides at least the same protections as the Act with respect to the disclosure and use of the data or information, and State law allows the data submitter to recover just compensation for losses that result from wrongful disclosure, as provided by the Act.

Public interim administrative review: The bill provides that a public interim administrative review initiated after January 1, 1987, on whether the use of a currently-registered pesticide or category of pesticides poses unreasonable adverse effects to the environment must be conducted as follows:

(1) The Administrator must publish criteria for initiating a review. The criteria must be based on levels of risk and could include consideration of currently available exposure data. Absence of exposure data would not delay initiation of a review. The Administrator could decline to initiate a review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

(2) As under current law, the Administrator could not initiate a review to develop a risk-benefit evaluation of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of the pesticide unless the review is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to the environment.

(3) On receipt of information about a pesticide demonstrating that the criteria for initiating a review have been met, the Administrator must notify all registrants of the pesticide and provide information and an explanation.

(4) If the Administrator intends to initiate a review of a pesticide registered for agricultural uses, the Administrator must notify the Secretary of Agriculture.

(5) Any review must be conducted in accordance with published regulations. The regulations must provide that a review will include a notice of initiation of the review; a notice of preliminary determination; and a notice of final determination. Public comment must be provided for in the notice of initiation and the notice of preliminary determination.

(6) The notice of initiation or the notice of preliminary determination must state the basis for the review or determination and request any additional data needed, and a bibliography of all scientific data, studies, and expert analysis concerning those risks or benefits of the pesticide that are under review. A person must submit comments within 90 days and disclose all scientific data, studies, and expert analyses in the person's possession about the pesticide that were not included in the bibliography.

(7) Within 18 months after initiating a review, the Administrator must decide what further regulatory action (if any) to take. (Sec. 301.)

Public hearings resulting from a public interim administrative review: The bill will establish the following special rules to govern hearings that result from the final decision of the Administrator in a public interim administrative review initiated after January 1, 1987:

(1) Any person who is adversely affected by a decision of the Administrator, including a person without an economic interest in the pesticide, could request a hearing within 30 days of the decision. A person could request a hearing, or intervene in a hearing, only if that person submitted comments during the review.

(2) At the request of a party to the hearing, the administrative law judge (ALJ) could receive into evidence portions of the review record and other evidence if the party demonstrates the evidence is relevant and material to the disputed issues, is not unduly repetitious, and a competent witness if made available to be cross-examined about the evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the review would not be admissible at the hearing. The right of parties to confront and cross-examine witnesses would be preserved on material issues of adjudicative facts.

(3) Not later than 120 days after the ALJ is appointed, prehearing matters must be completed and the hearing begun. The ALJ could establish a schedule for prehearing matters, and must ensure that the hearing schedule is met.

(4) Any challenge to the notice of intent to cancel or change classification stemming from the review, or to any request for a hearing or motion to intervene, must be filed with the ALJ before the evidentiary phase of the hearing. Not later than 30 days before the hearing begins, the parties must exchange witness lists, a summary of testimony, and a list of all documents and exhibits to be introduced at the hearing. The presentation of evidence must be completed within 60 days after commencement of the hearing. The person who requested a hearing on an issue will have the burden of going forward to present an affirmative case and have the burden of proof on that issue.

(5) A hearing must be completed and the Administrator must make a final decision within 300 days of the issuance of the final review notice that gave rise to the hearing. (Sec. 302.)

Cancellation and change in classification on labels: The bill will add a new provision to current law to require that any request for a hearing on cancellation must identify the findings and conclusions of the Administrator that are disputed, and include a complete statement of the reasons and factual basis that support the request for a hearing. Any party may identify findings and conclusions in dispute. Before convening a hearing on the request of a person without an economic interest in the pesticide, the Administrator must determine that the request presents a substantial issue of fact pertaining to whether the pesticide poses an unreasonable risk to man or the environment.

The bill also will authorize pesticide label changes that could be required by the Administrator through informal rulemaking, as follows:

(1) The Administrator could not require label changes that are equivalent to a cancellation of a use, render the product unmarket-

able, or otherwise have a major economic effect on persons affected by the changes.

(3) Once a regulation is promulgated, the Administrator must notify each registrant or user of the pesticide of the label change required by the regulation. Thirty days must be provided for registrants to apply for amendments to registrations to comply with the regulation.

(4) At a hearing requested by a registrant or user of a pesticide that is subject to the regulation, the scope of the hearing will be limited to whether—

(a) the pesticide complies with the regulation;

(b) the regulation by its terms is applicable to the pesticide; and

(c) because of significant new information it would be unreasonable to require compliance with the regulation.

(5) In an action for review of a label regulation, on request, the court must stay the regulation if the petitioner shows a likelihood of success on the merits, and that implementation of the regulation would cause a risk of substantial harm to the petitioner. The court could not stay the regulation if the Administrator shows that failure to implement the regulation would cause a risk of substantial harm to health or the environment. (Sec. 303.)

Public hearings on cancellation: The bill provides that, as soon as practicable after completion of a hearing on the cancellation of a pesticide registration (but not later than 18 months after the issuance of the cancellation notice that gave rise to the hearing), the Administrator must evaluate the data and reports and take appropriate regulatory action. This time period could be extended by the Administrator under extraordinary circumstances for not more than one year. (Sec. 304.)

Administrative changes: The bill will allow a pesticide registrant any time to request that any of its registrations be cancelled or amended to delete one or more uses. Before acting upon the request, the Administrator would be required to publish a notice of the receipt of the request.

The bill will specify that notices of certain regulatory action under the Act must be published in the Federal Register and sent by certified mail, return receipt requested, to the registrant's or applicant's address of record.

The bill will restate and clarify existing law to require that if, at any time after registration a registrant has additional information regarding unreasonable adverse effects of his pesticide on the environment, the information must be submitted to the Administrator. Information would include factual information and expert opinion regardng risks or benefits.

The bill provides that, if the Administrator issues a notice of the denial of registration, a request for a hearing under the Act must be made within 30 days after receipt of the notification. The Administrator could issue regulations governing the right to a hearing on denial with respect to a product containing an ingredient that already has been cancelled under the Act. The regulations could give due weight to the desirability of finality of prior proceedings and the extent the applicant had an opportunity to participate in earlier proceedings. (Sec. 305.)

Cancellation of registration based on false or invalid data: The bill will require the Administrator to immediately issue an order of suspension and a notice of intent to cancel a pesticide registration if the Administrator has determined in the Industrial Biotest validation process that the data submitted in support of the registration were invalid and have not been replaced, or are in the process of being replaced but are not submitted by April 1, 1988, and are material to the registration.

The bill specifies that, if the Administrator determines that invalid data have been submitted or cited in support of a registration, the Administrator could either require the registrant to submit valid replacement data on an expedited schedule, or issue a notice of intent to cancel the registration. If a registrant willfully submits material data known to be false in support of registration, the Administrator must immediately issue a notice of intent to suspend or cancel the registration.

The bill will make a suspension or cancellation based on false or invalid data effective 30 days after receipt by the registrant of a notice of the proposed action unless, during the 30-day period, a request for a hearing is made by a person adversely affected.

The bill will limit the matters for resolution at hearings held with respect to false or invalid data and impose a 75-day time limit on the hearing. (Sec. 306).

Inspections: The bill will clarify existing law to provide that officers or employees of the United States or of any State, duly designated by the Administrator are authorized to—

(1) conduct inspections at pesticide distribution and sales facilities, other places where pesticide records are located, and pesticide testing facilities;

(2) enter any place where the officer or employee has reason to believe that the Act has been or is being violated by any person other than a private applicator;

(3) execute warrants authorizing entry, inspection, and obtaining of evidence for inspection purposes, inspection and copying of records, and seizure of any pesticide or device that is in violation of the Act; and

(4) execute warrant if there is probable cause to believe a criminal violation of the Act has occurred or is occurring on the property to be entered or that evidence of a criminal violation of the Act will be found on the property.

The bill will require the Administrator to coordinate inspections with actions taken under other Federal laws. (Sec. 402.)

Export of pesticides: The bill specifies that a pesticide will be considered misbranded if the pesticide is intended for export and is substantially similar in composition and use pattern to a registered pesticide but the label is not written, in an appropriate language or does not contain the same health, safety, and hazard precautions as a registered pesticide, unless the precautions on the label would be in conflict with laws of the importing country.

This bill will restrict the export of a pesticide that is classified for restricted use, cancelled, suspended, or not registered for any use. Export of the pesticide would be allowed if 30 days before the first shipment each year, the Administrator (1) provides the notice described below to the appropriate government regulatory office in the importing country, and (2) prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that the pesticide is not registered and cannot be sold in the United States. The notice must be made in an appropriate language and contain information relating to the pesticide, the exporter and importer of the pesticide, the appropriate government regulatory office in the importing country, reasons why the registration was canceled, suspended, withdrawn, classified for restricted use, or not registered, and the location of the EPA office that can provide additional information. (Secs. 501 through 504.)

Certification, training, and recordkeeping: The bill will make it a violation of the Act for any person to use any pesticides as a commercial applicator unless the person is a certified commercial applicator, or a registered commercial applicator under the direct supervision of a certified commercial applicator. To be considered to be a certified commercial applicator or a registered commercial applicator a person must meet certain requirements and standards.

The bill provides that a restricted use pesticide must be considered to have been applied by, or under the direct supervision of, a certified private applicator only if it is applied by a person who is either a certified private applicator, or a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator. To be considered to be a certified private applicator or supervised private applicator a person must meet certain minimum requirements and standards.

The bill will impose a requirement that each certified applicator and each registered commercial applicator undergo refresher training and be recertified or reregistered within a period established by the State agency but not to exceed 5 years.

The bill will require the Administrator in consultation with the Secretary of Agriculture to develop certain training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable law, regulations, and labeling. The bill also will require the Administrator to establish minimum standards of competency, and experience or expertise mimimum standard of competency, and experience or expertise for trainers and minimum standards for training programs.

A State agency could approve any privately administered training program that it determines meets the requirements established under the Act, or requirements established by the State agency, whichever are more stringent.

Federal and State field personnel responsible for on-site observations and inspections of pesticide use must have training that includes training covering materials specified for the commercial application categories for which they are assigned enforcement responsibility.

The bill also will clarify that, in establishing standards applicable to applicators, the Administrator must establish separate standards for commercial applicators and private applicators. (Sec. 601.)

The bill will require each commercial applicator to maintain records of pesticide applications, including the identity and amount of the pesticides applied and the date and location of the applications, for a period of two years. No regulations could require any private applicator to maintain any records or file any reports or other documents.

Each pesticide dealer would have to maintain a record of each sale or distribution of a pesticide classified for restricted use and pesticides designated because they may cause significant adverse effects on health or the environment. The records must include the identity of the pesticide sold, identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer must maintain the records for three years.

A pesticide dealer or commercial applicator must afford to any employee or former employee access to records required to be kept that directly relate to the employee's employment duties. Customers of the dealer or applicator must also have access to records that directly relate to a purchase or application.

State enforcement agencies, as part of an investigation or enforcement action in response to a formal complaint, must make available a report of the findings of the investigation or action to the complainant. At a minimum, the report must include the records required by this section.

An employer who uses or supervises the use of a pesticide must know or have access to the brand name and common or chemical name of each ingredient listed on the labeling of the pesticide, and know or have access to the safety, first aid, and antidote information listed on the labeling, and make the information available, on request, to any employee exposed to a pesticide and to treating medical personnel.

Records obtained under these provisions of the bill that are used for commercial purposes would be a violation of the Act. (Sec. 601.)

Defensive data: The bill provides that if the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide or the existing registrations of a group of pesticides, the Administrator must notify the registrant of each pesticide to which the determination relates and provide a list of such registrants to any person. Each registrant of the pesticide must provide evidence within 90 days after receipt of notification that the registrant is taking appropriate steps to secure and submit the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of development of, such data. Any registrant who enters into such an agreement, or who offers to agree to share in the cost of development of such data, shall be entitled to examine such data and rely on such data to maintain or obtain registrations under this Act or under the law of any State. An offer to enter into such an agreement may be accepted at any time and may not be withdrawn without the consent of the person to whom the offer was made. If at the end of 60 days after two or more registrants have entered into an agreement the registrants have not further agreed on the terms of the data development or cost-sharing agreement or on a procedure for reaching such agreement, any of the registrants may initiate binding arbitration proceedings to fix such terms by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by the Service. (Sec. 701.)

Data compensation and arbitration: With respect to the amount of compensation that must be paid when a person wishes to use another person's data to register a pesticide, the following rule is applicable. In the case of a pesticide whose patent term has expired, the terms and amount of compensation for data that was submitted for the pesticide to be paid by a person who intends to file an application for registration of a pesticide that cites the data may be fixed before the submission of such application by arbitration initiated by such person. The arbitration would be binding on the original data submitter and would be binding on the applicant after the date the application is submitted. The findings and determination of the arbitrator would be subject to judicial review in the United States Court of Appeals upon the filing of an action by a party to the arbitration up to the date the person submits the application. The findings and determination of the arbitrator with regard to issues of fact must be sustained if they are supported by substantial evidence when considered on the record of the arbitration as a whole. Each party to the first arbitration to determine the terms and amount of compensation for the use of particular data would share equally in the payment of the fees and expenses of the arbitrators and would each pay its own attorney's fees. In all subsequent arbitrations to determine the terms and amount of compensation for the use of the data, the party to the subsequent arbitration who seeks to cite the data of the original data submitter must pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter. (Sec. 702.)

Restoration of patent term; patent infringement: The bill restores patent life to pesticide products whose patent terms are eroded by mandatory Federal premarket testing before its commercial marketing or use. The bill also provides, generally, that it would not be an infringement of a pesticide patent to make, use, or sell the pesticide solely for testing purposes or to obtain a tolerance exemption during the last two years of the patent term. However, the bill also provides that if a patent term is restored for less than two years, the period during which testing may occur without infringement would begin one year before the patent expires. (Sec. 703.)

Authority of States: The bill provides that States may not prohibit the sale of certain house or garden pesticides for which an application for State registration has been filed unless and until the State has acted pursuant to applicable State law.

The bill also specifies that when a State provides a registration for additional uses of a Federally registered pesticide to meet special local needs, the registration will expire and be of no further effect at the end of the period, if any, provided by the State, or 10 days after the date the Administrator publishes a notice that the State no longer desires the registration to continue in effect.

The Administrator must establish criteria that define the conditions under which a special local needs registration may be disapproved by the Administrator, taking into account geographic patterns of use.

The bill also provides for national uniformity in the regulation of residues of pesticides in or on food in order to facilitate national production and marketing of all foods without jurisdictional barriers. In addition, the bill permits a State to petition for an exemption from the national level of residue of a pesticide if a different requirement is justified by compelling local conditions, would not unduly burden interstate commerce, and would not cause any food to be in violation of Federal law. The bill would also allow a State to establish a requirement for the pesticide residue in or on food which differs from the uniform requirement in cases of an imminent hazard until the EPA Administrator acts upon a State's petition for such differing requirement. (Sec. 801.)

Definitions: The bill will clarify that the term "to use any registered pesticide in a manner inconsistent with its labeling" does not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, unless the labeling specifically prohibits a deviation; or (2) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling. (Sec. 802.)

Information requested: The bill will require the Administrator to catalogue and retrieve data under the Act in a manner to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data. (Sec. 803.)

Scientific advisory panel: The bill will make the scientific advisory panel under the Act permanent and expand the panel from 7 members to 9 members. (Sec. 805.)

Authority for EPA action: The bill provides that the Administrator could act upon complaints or information, if a State does not promptly initiate appropriate investigative action after receiving a referral from the Administrator, or does not initiate appropriate enforcement action within 90 days of receipt of the referral. (Sec. 806.)

Expiration of State primary enforcement responsibility: The bill provides that the primary enforcement responsibility of a State with respect to pesticide use violations will expire on January 1, 1990, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in the Act. (Sec. 807.)

Unlawful acts: The bill provides that it would be unlawful for any person to—

(1) falsify all or part of any records required to be maintained under the Act;

(2) falsify all or part of any information relating to the testing of any pesticide;

(3) submit data known to be false to the Administrator in support of a registration; or

(4) violate certain regulations issued under the Act. (Sec. 808.)

Penalties and subpenas: The bill provides that—

(1) any registrant, applicant for a registration, or pesticide testing facility that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than

$25,000 for each offense, and not more than $50,000 for a subsequent violation;

(2) any commercial applicator of restricted use pesticides, or any other person who distributes or sells pesticides or devices, that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $10,000 for each offense, and not more than $20,000 for a subsequent violation;

(3) any private applicator who violates any provision of the Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense, and not more than $2,000 for a subsequent violation. The Administrator could waive the requirement for a warning of citation for a first offense by a private applicator if the violation was intentional or caused significant harm to health or the environment;

(4) any registrant, applicant for a registration, or pesticide testing facility that knowingly violates any provision of the Act must be fined not more than $50,000 or imprisoned for not more than 2 years, or both. Any commercial applicator of restricted use pesticides, or any person (not including a registrant, applicant for registration, or pesticide testing facility) who distributes or sells pesticides or devices that knowingly violates any provision of the Act must be fined not more than $25,000 or imprisoned for not more than 2 years, or both.

The maximum penalty for the knowing violation of the Act by a private applicator would be increased from $1,000 to $2,000, and the possible term of imprisonment from 30 days to 60 days.

The Administrator could issue subpenas compelling the attendance and testimony of witnesses, and production of documents. (Sec. 809.)

Congressional review: The bill will repeal current congressional veto provisions applicable to regulations under the Act. Substitute provisions would be provided for the Administrator, simultaneously with the promulgation of any rule or regulation, to transmit a copy to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation would not become effective until 60 calendar days after the rule or regulation is transmitted. (Sec. 810.)

Review of regulations: The bill will allow any person to obtain judicial review of a regulation promulgated by the Administrator, or the refusal by the Administrator of a petition to modify or rescind a regulation, filing a petition for review in the United States court of appeals within 120 days after the date of promulgation or refusal.

A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under the Act would not be subject to judicial review in any suspension, cancellation, or denial proceeding, or in any appeal therefrom, or in certain enforcement proceedings under the Act or in any appeal therefrom, except on request of an agricultural producer who is adversely affected by the action. If a person petitions the Administrator to modify or rescind a regulation in the enforcement proceeding, the application of the regulation must be stayed until the Administrator issues a final decision on the petition. (Sec. 811.)

Delegation and cooperation: The bill will establish that regulatory actions of the Administrator will not preempt the Secretary of Labor from acting under the Occupational Safety and Health Act to prescribe or enforce standards or regulations to the extent that the Administrator and the Secretary of Labor so agree. To ensure the safety and health of workers, the Administrator and the Secretary of Labor must seek to reach agreements and to coordinate the exercise of their statutory authority. (Sec. 812.)

Indemnity report: The bill provides that if the Administrator has taken an action that requires the payment of indemnification, the Administrator must provide a report to the House and Senate Agriculture Committees and the House and Senate Appropriations Committees. The Administrator would be prohibited from making such payment unless a specific line item appropriation of funds had been made in advance for the payment. (Sec. 813.)

Groundwater authority: The bill will provide, and require the Administrator to use, additional authorities to protect drinking water and groundwater against contamination by pesticides. The Administrator must consult with, and take into account the views of, the States and the Secretary of Agriculture in exercising this authority. (Sec. 814.)

Worker health and safety: The bill will require the Administrator to promulgate regulations for the protection of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas. The Administrator also must promulgate regulations that provide for the training of employees who mix, load, or apply pesticides. (Sec. 815.)

Neurotoxic and behavioral effects of pesticides: The bill will require the Administrator (1) to develop methods to more accurately detect neurotoxic and behavioral effects of pesticides and pesticide ingredients; and (2) as such methods are developed, to provide that testing data be submitted by persons seeking to obtain or maintain pesticide registrations. (Sec. 817.)

Pesticide containers: The bill will require the Administrator to promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides and regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal. The bill also requires the Administrator to conduct a study of options concerning pesticide containers and to report to Congress the results of the study. (Sec. 818.)

Liability: The bill will establish that—

(1) an agricultural producer will not be liable in any action brought under any Federal statute for damages caused by pesticide use unless the producer has acted negligently, recklessly, or intentionally. Proof that a pesticide was applied in accordance with label instructions will create a rebuttable presumption that the agricultural producer did not act negligently; and

(2) nothing in this section may be construed as conferring a private right of action on any person for the purposes of this Act or any other Federal law. (Sec. 821.)

IR-4 program: The bill will require the Secretary of Agriculture to provide support for the interregional project number 4 program (commonly referred to as the "IR-4 program"). (Sec. 822.)

Pesticide risk rating: The bill will authorize the Administrator to contract with the Board of Agriculture of the National Academy of Sciences to conduct a study to determine the feasibility of establishing an environmental risk rating for pesticides used in the production of agricultural commodities and report the findings of the study to the Administrator and to the House and Senate Agriculture Committees. (Sec. 823.)

BACKGROUND

I.

Pesticides are substances used to control many kinds of pests: insects that attack crops, destroy materials, and carry disease, nematodes, weeds, fungi, and others. They have become an important component of agricultural production and health protection. Against their benefits, certain hazards must be weighed. Pesticides may be toxic. Some persist in the environment and many pose risks to nontarget organisms.

Federal regulation of pesticides began in 1910 with passage of The Insecticide Act (P.L. 61-1520). The Act, administered by the Department of Agriculture, protected farmers by preventing the manufacture, sale, or transportation of adulterated or misbranded insecticides and fungicides.

During World War II, synthetic organic pesticides were developed for use in the War effort. After the War, the pesticide industry epxanded rapidly. In 1947, Congress repealed The Insecticide Act with passage of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The law remained under the jurisdiction of the Department of Agriculture. A primary purpose of FIFRA was to protect farmers from ineffective and dangerous pesticides by requiring all pesticides to contian registered labels. The regulatory mechanism to control pesticide use was imposed through the requirement that before a pesticide could be marketed, it must have been granted a "registration". A product would be registered either on the basis of the Department's conclusions about what uses were safe and what use restrictions were necessary, or over the objeciton of the Department.

Over the next two decades, concern grew about hazards to health and the environment from pesticides, but FIFRA remained fundamentally unchanged. However, in 1959 FIFRA was amended (P.L. 86-139) to expand the pesticide products covered to include nemotocides, plant regulators, defoliants, and dessicants. In 1964, following the recommendations of the President's Science Advisory Committee report entitled Use of Pesticides, FIFRA was amended (P.L. 88-305) to eliminate the "protest registration" that allowed a manufacturer to market a pesticide even if the Department of Agriculture refused to approve it. The legislation set up a new method by which manufacturers and the Department could resolve differences concerning registration. The manufacturer could request a hearing or a scientific review committee. The legislation also provided a mechanism for the Secretary of Agriculture to suspend a pesticide registration, thereby immediately halting its sale in interstate commerce. Finally, it permitted the label of a pesticide to bear its registration number (previously a label could not indicate it was registered, so as to avoid any appearance of Department endorsement of the product).

When the Environmental Protection Agency (EPA) was created in 1970, authority to implement the pesticide statute was transferred from the Department of Agriculture to EPA.

The Federal Environmental Pesticide Control Act of 1972 (P.L. 92-516) completely rewrote FIFRA. The new FIFRA provided for direct controls over pesticide use, for classification of selected pesticides into a restricted category, for registration of manufacturing plants, and for a national monitoring program for pesticide residues. It also added environmental effects to the risks to be weighed in the pesticide registration process.

For the first, EPA had difficulty with its pesticide regulation program and with implementing the 1972 amendments. The agency frequently found itself being criticized by proponents for greater regulation of pesticide use and by those urging less government interference in the pesticide field.

The Federal Pesticide Act of 1978 (P.L. 95-396) culminated 6 years of efforts to overcome implementation obstacles and other problems arising from the 1972 amendments to FIFRA (some amendments had been added in the 1975 reauthorization).

The 1978 Pesticide Act expedited the registration process by providing for registration on the basis of the generic chemical (i.e., active ingredient), allowing conditional registration, developing limited data requirements for minor use pesticides, and providing the developer of a new pesticide chemical with a 10-year period of exclusive data use. In addition, States were given primary enforcement responsibilities for the Act. To improve EPA's risk assessment analyses that lead to decisions by the Administrator, the new Act required the agency to obtain guidance from its Scientific Advisory Panel. The 1978 Act also required EPA, in coordination with the Department of Agriculture, to conduct research into integrated pest management.

II.

The purpose of S. 2792, as reported by the Committee, is to extend the authorization for appropriations for the pesticide program under the Federal Insecticide, Fungicide, and Rodenticide Act through September 30, 1991; strengthen the protection of public health and the environment; increase public confidence that pesticides are approved and used in a manner consistent with current health and safety requirements; and ensure that pesticide users, including agricultural producers, will have access to the effective and affordable products they need on the farm, in the workplace, and at home. S. 2792 also ratifies a number of policies in current practice at EPA.

Several of the important provisions of S. 2792 are based on the landmark agreement reached in 1985 proposing substantial revisions to FIFRA. This accord was reached by the National Agricultural Chemicals Association, representing some 92 pesticide manufacturers, and the Campaign for Pesticide Reform, comprised of 41 environmental, consumer, and labor organizations. The compromise effort was eventually endorsed by the American Farm Bureau Federation.

The need for the revisions to FIFRA is well documented. In recent years, the General Accounting Office, the National Academy of Sciences, and others have reported on the slow pace of EPA's progress in completing the reregistration of existing pesticides according to current health and safety standards. The reregistration effort has lagged because of inadequate resources and the sheer magnitude of the task.

The 1972 FIFRA amendments required review of all then-registered products to reassess and ensure their safe use, and continued the prior law's requirement that registrations be renewed every 5 years. The general reregistration requirement was originally ordered to be completed by 1975, but the deadline, after a brief extension, was dropped altogether in 1978.

As a part of its current reregistration efforts, EPA is developing "registration standards" for each of the approximately 600 pesticide active ingredients that it deems to be commercially important. Development of these reregistration standards entails a review of the data on each active ingredient, a preliminary step, to determine the adequacy of existing data and the need to require registrants to generate studies to replace missing or inadequate data. The EPA has completed just 127 "interim" reregistration standards and is able to issue only about 25 such interim standards each year.

According to an April 1986 report by GAO entitled "Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks":

> Based on current program and resources projection, it appears that reregistration will extend into the 21st century. EPA has been developing about 25 interim registration standards a year and expects to complete these preliminary reassessments around the year 1996. The Agency plans to complete final regulatory standards and tolerances reassessments after receipt and review of all required test data by the year 2005, assuming an increase in resources beginning in fiscal year 1988. The Agency expects that these final standards may cost as much to develop, in both time and resource, as interim standards. As of March 31, 1986, about 17 active ingredients are ready for the development of final registration standards, 12 of which have essentially completed reassessment, accordance to EPA officials. EPA plans to complete the first final standard in fiscal year 1986. Yet to be done is the reregistration of individual pesticide products following development of final registration standards. Further, EPA will have to maintain final standards to preclude another costly reregistration-type effort sometime in the future.

The slow pace of pesticide reregistration in large part explains why an accelerated reregistration scheme is made the centerpiece of S. 2792.

Moreover, concern about the lack of data sufficient to support current pesticide registrations has led to demands for reform in EPA's public interim administrative review and the cancellation process; reinforces the desire by States and their political subdivisions to seek increased control over pesticide use and pesticide residues in food; prompt calls for more stringent protections for workers exposed to pesticides; and increases the efforts to limit pesticide use. Consequently, the polarized public debate that surrounds pesticide use cannot be expected to subside until a successful reregistration program restores confidence in the regulatory system that governs pesticide approval and use.

Another area of concern addressed in the bill is the detection of pesticides in drinking water and ground water as a result of normal product use. While FIFRA gives implicit authority to EPA to regulate pesticides in ground water FIFRA does not specifically mention ground water. The potential of pesticides entering ground water is addressed in the overall regulatory approach of FIFRA, in the Agency's authority to prevent the sale and distribution of pesticides that cause unreasonable adverse effects on the environment. Ground water is sufficiently important, however, that more explicit guidance should be provided to the Administrator to ensure the resource receives appropriate attention.

Ground water is a vast water resource, present in geological formations or aquifers beneath the land surface, and is extremely important. It supplies drinking water to over 50 percent of the U.S. population, through about 48,000 community water systems and 12 million individual wells. Approximately 95 percent of rural households depend on ground water for drinking, agricultural production, and other uses.

Until recently, ground water was thought of as a pristine resource, unspoiled by human activities. Most people believed that the soil was capable of binding and holding chemicals, such as pesticides applied to its surface, and that the chemicals themselves decomposed in the soil by biological and chemical activity. While this is true for many chemicals, scientists have learned that certain chemicals under certain conditions may enter the ground water. With the importance of ground water to agriculture and rural drinking water supplies, careful scrutiny of the potential for pesticides to enter ground water is essential. It is possible that, without the further preventative measures included in this amendment, and with expanded future monitoring activity and pesticide use, additional findings of pesticides in ground water will appear in the next several years.

Both Federal and State governments are actively engaged in learning more about ground water and in its protection. States and localities have exercised primary responsibility for protecting and managing ground water. Ground water quality management and protection programs at such levels have varied greatly in their approaches and strategies. Many States have supplemented their general, implicit authority over ground water quality with specific legislation, policy statements, and regulatory programs. There still remains a need on the Federal level, in the context of existing national registration of pesticides, to address specifically regulation of pesticide use with respect to ground water.

Committee Consideration

HEARINGS

On Tuesday, April 22, 1986, the Committee on Agriculture, Nutrition, and Forestry met to hear testimony on legislation to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This hearing, the first of two sessions, was chaired by Senator Richard Lugar. Senator Lugar explained that the purpose of the hearing was to elicit recommendations from interested parties regarding the most advisable way for the Committee to proceed in reauthorizing FIFRA.

Senator Lugar summarized two options to be considered by the Committee as: (1) compromise legislation (S. 2215, introduced by Senators Lugar, Leahy and Proxmire) supported by the National Agricultural Chemical Association (NACA) and the Campaign for Pesticide Reform; and (2) a bill (S. 2346) supported by the Chemical Specialties Manufacturing Association and American Farm Bureau Federation. This legislation was introduced by Senator Jesse Helms, Chairman of the Committee on Agriculture, Nutrition, and Forestry.

Senator Lugar commended Committee members and interested parties for the open-minded spirit of bipartisanship and cooperation they had displayed thus far. He noted there were still many differences to be overcome and compromises to be made in order to keep the negotiations going. He suggested that the sheer bulk of relevant issues and differences would have to be reduced in order for the Committee to complete action on a bill this year, and urged Committee members and interested parties to "consider narrowing the scope of these issues." He suggested specific ways the Environmental Protection Agency (EPA) could help accomplish these goals.

The Honorable Jack Moore (Assistant Administrator, Pesticides and Toxic Substances, EPA) opened the morning testimony by asserting that EPA was making significant progress in a number of areas. He called attention to the Agency's progress in registration of new pesticides and envisioned a scenario of new, safe chemicals working to improve American agriculture in the future. Praising the current statute, Mr. Moore nevertheless suggested that Committee members use the reauthorization process to eliminate FIFRA's more cumbersome aspects. Expressing overall satisfaction with the current pesticide regulatory program, he suggested speeding up the reregistration of older pesticides. He mentioned several improvements which would have that effect. Mr. Moore said the biggest reason for prolonged reregistration was that under current law EPA is required to do much labor-intensive work just to evaluate old pesticides by current health and safety criteria. He explained that this was not a legitimate EPA function, and that such work should be done by registrants themselves.

For the remainder of his testimony, Mr. Moore outlined in specific detail several additional modifications EPA would like to see made. Principal among those were effective regulation of inerts, higher competency standards for certified pesticide applicators, adequate enforcement responsibility and comprehensive reform of fee structures for the pesticide regulatory activities performed by EPA.

Next to testify was Ms. Karen Darling, Deputy Assistant Secretary, Marketing and Inspection Service, U.S. Department of Agriculture (USDA). While acknowledging that unnecessary delays in the regulatory process were in no one's best interest, Ms. Darling added that any changes should not hinder EPA's ability to base its actions on sound scientific data. The EPA Administrator, she said, should have flexible timetables for getting the necessary work done. Ms. Darling noted that S. 2215 "does not provide for notification of the Secretary of Agriculture when an interim administrative review is initiated." Automatic notification should be part of the bill, she said, adding that USDA should be involved in any cancellation or classification review process. Ms. Darling also took exception to the bill's intent to eliminate the requirement that the Agriculture Secretary's approval be sought for certain actions relating to minor-use pesticides.

On the question of fees for reregistration of pesticides, Ms. Darling expressed USDA's concern that fees could become a disincentive to the development of minor-use products. The Department's position, she said, is that exemptions from prospective fees should be granted only for the IR-4 projects dealing with minor uses and for Federal agencies holding pesticide registrations. Ms. Darling also expressed concern that S. 2215 would amend FIFRA's provisions regarding the export of pesticides by mandating the revocation or amendment of tolerances and food additive regulations within 60 days of cancellation or other changes in the registration status of a pesticide. USDA believes such an amendment could encourage America's trading partners to restrict U.S. exports, she said. Ms. Darling asserted that the question of tolerance revocation for cancelled pesticides is better addressed in other forums (not FIFRA), such as the World Health Organization and EPA. She said that EPA's authority to establish tolerances and food additive regulations comes from the Federal Food, Drug and Cosmetic Act rather than FIFRA.

Senator Lugar then introduced a panel of experts who would be giving testimony before the Committee. They were: Dr. Jack Early, President, NACA; Ms. Nancy Drabble, Director of Public Citizens Congress Watch, Washington, D.C.; and Mr. Al Meyerhoff, Senior Attorney with the Natural Resources Defense Council, San Francisco, California. Dr. Early spoke first. He was accompanied by Mr. Carl J. Kensil, Vice President of CIBA-GEIGY Corporation, and W. Scott Ferguson, general counsel, NACA.

Dr. Early expressed NACA's strong support for S. 2215. Citing the bill's potential for bringing the totality of pesticide registrations up to date, he predicted that passage of S. 2215 would give farmers peace of mind and more confidence in agricultural chemical technology.

Dr. Early addressed the fears of some user groups concerning the prospective elimination from the market of agrichemicals used on minor crops as a result of the proposed $150,000 reregistration fee. Dr. Early suggested that the cost of generating necessary data for reregistration was enormous relative to the reregistration fee. He said some older products (minor-use agrichemicals) would inevitably disappear regardless of whether S. 2215 is enacted or not. Dr. Early reiterated NACA's previous offer to provide resources to EPA in order to speed up the process. He cited several advantages to this, and explained that NACA's innovative capabilities (which require much scientific know-how and high-risk capital investment) were being hindered by the Federal Government. NACA loses patent life to FIFRA's regulatory requirements, he said. Dr. Early went on to explain the effects of loss of patent life.

Mr. Kensil then detailed some of the differences his industry has had with its traditional adversaries, asserting that CIBA-GEIGY Corporation fully accepts its responsibilities to the public. He then re-emphasized CIBA-GEIGY's full support for the reforms included in S. 2215.

Ms. Drabble discussed the negotiating process through which a coalition of groups with competing differences had come together to support S. 2215. Industry, environmental and consumer groups had all been deadlocked for years on the subject of amending FIFRA. Ms. Drabble cited the hundreds of hours in discussions between groups with competing interests and Federal officials, as having produced the desired compromises. She expressed her hope that Committee members would not undermine the delicate balance of compromises necessary to achieve a passable bill.

Mr. Meyerhoff testified next, detailing some of the provisions of the legislation before the Committee. He focused particularly on the issues of reregistration and cancellation procedures. Mr. Meyerhoff lamented the small universe of pesticide active ingredients (marketed in the United States) which have actually been reregistered over the past several years. He asserted that many users do not have adequate data necessary to make full health and hazard assessments. "We have been regulating out of ignorance," he declared.

Mr. Meyerhoff detailed some of the efforts being made to correct this problem, a process he said was vital to the final equation. He called for passage of a bill this year.

Chairman Lugar opened the afternoon session by introducing a new panel for testimony. Included were: Mr. Mark Maslyn, Assistant Director, National Affairs Division, American Farm Bureau Federation (AFB) and Mr. Ron D. White, consultant to the Texas State Department of Agriculture.

Mr. Maslyn claimed that S. 2215 was by and large "acceptable" to the AFB. He stated, however, that his organization had serious problems with provisions of the bill affecting producers of so-called "minor-use crops." The establishment of reregistration fees was of particular concern to AFB, he said. Specifically, Mr. Maslyn contended that the additional costs of the fees would be passed along, driving up production costs to farmers and ranchers and further eroding net farm income. He also expressed concern that such fees would set a dangerous precedent of user fees for agricultural chemicals. Beyond the specter of higher priced products, Mr. Maslyn expressed AFB's belief that "the combined effects of an expedited and rigid reregistration schedule, and the additional requirement of fees could hasten the removal of some products from the marketplace, leaving farmers without adequate means to protect their crop investments."

The AFB believes that farmers and ranchers must be protected from liability to individuals who legally abide by federally approved label directions, employ standard farming practices, adhere to the recommendations of USDA extension service and demonstrate their proficiency through training and certification programs. This is not only fair but environmentally sound.

Mr. Maslyn also expressed AFB's opposition to a citizen suit provision (or private right of action). Specifically, AFB's fear is that farmers will be harassed with nuisance suits alleging violations of FIFRA in the course of normal farming procedures.

Mr. White opened his testimony by voicing support for deadlines on reregistration of old pesticides. He claimed it would be in the best interests of achieving a workable budget to do so. He also called for accelerated product testing, citing the need for EPA to have all available information before developing a groundwater monitoring strategy. Accelerated product testing is important for many reasons, he said, one of which is effective state enforcement of FIFRA. Mr. White called for increased USDA funds for IR-4 programs, implying that the loss of products in reregistration (or more specifically, loss of protection for farmers' crops) was nothing that a larger IR-4 budget couldn't fix. He also expressed concern with problems related to inert ingredients.

Mr. Feldman of the National Coalition Against the Misuse of Pesticides closed out the day's testimony with a call for balanced treatment in the Committee's handling of "the pesticide safety equation." One-sided treatment of this issue, he warned, will result in widespread contamination and poisoning. Specifically, Mr. Feldman produced several studies (focusing on cancerous death rates among licensed pesticide applicators) to buttress his contention that the pesticide control system is failing. In those areas where people are directly exposed to materials, he said, the danger of cancer is strongly asserting itself.

Pesticide residues in foods are a serious health hazard, Mr. Feldman declared. Other clear and present dangers include indoor exposure to pesticides and groundwater contamination. He blamed these problems on misuse of pesticides combined with inadequately registered and regulated pesticides. Mr. Feldman expressed the view that the Nation was in the midst of a "crisis" which S. 2215 could help contain. To help deal with this "crisis," Mr. Feldman suggested a private right of action after an individual has exhausted administrative remedies. He further suggested that Committee members strengthen the authority of localities (to establish notification provisions) as a "right to know" measure.

Mr. Feldman then engaged in a dialogue with Senator Lugar, during which he stated that the "bottom line" was pesticide contamination or poisoning. Senator Lugar took exception with him on the issue of user liability exemptions. Mr. Feldman asserted that merely following instructions for proper use was not enough to avoid responsibility for consequences. Senator Lugar also challenged Mr. Feldman on his testimony regarding state and local regulatory issues, stating that pesticide producers should not be expected to amend their business operations in order to satisfy the concerns of many local jurisdictions across the country that may decide to legislate in this area.

On Thursday, April 30, 1986, the Committee met to hear further testimony regarding legislation to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Chairman Helms explained that the purpose of the hearing was to elicit recommendations from interested parties regarding the most advisable way for the Committee to proceed in reauthorizing FIFRA for fiscal year 1986.

The first panel of witnesses introduced by the Chairman were Mr. Ralph Engel, President, Chemical Specialties Manufacturing Association, accompanied by Dr. Warren E. Stickle, Director of Legislative Affairs; Mr. Harvey Gold, Executive Vice President, National Pest Control Association; Mr. Earle K. Borman, Jr., Vice President, Sterling Drug Inc.; and Mr. Robert M. Russell, Vice President of Government Relations, Orkin Pest Control.

Mr. Engel opened the morning's testimony with a strong endorsement of S. 2346, introduced by Senator Helms. He stated that the bill has unrealistically optimistic re-registration timetables, adding that the Environmental Protection Agency (EPA) could do the job much better given more time. Noting that Congress has consistently taken steps to prohibit user fees for the registration of drugs, he specifically took issue with provisions in S. 2215 which single out pesticides for special user fees (when other preclearance statutes are specifically exempt form user fees or registration fees).

Citing the prohibitively high cost of re-registration fees—a serious financial strain on small manufacturers—Mr. Engle declared his organization's opposition to any reregistration fees. He raised the additional possibility that exorbitant re-registration fees could one day determine which antimicrobial products are available in the marketplace. Fees should not determine the availability of products, he said.

Praising EPA's renewed interest in inert ingredients, he nevertheless took issue with related provisions of S. 2215. He said his organization disagrees that widespread exposure should, alone, be a trigger to the listing of inert ingredients, thus requiring additional testing. An inert ingredient should be listed only if a risk assessment, or hazard evaluation indicates that a significant hazard may exist in the use of pesticide products, he said. Mr. Engel agreed that troublesome inerts should be labeled if they precipitate potential danger in end-use pesticides. And yet he suggested that criteria for determining if significant hazards exist be rigid enough to prevent inerts from being wrongfully listed as "hazardous." Mr. Engel suggested that a ceiling be placed on the number of inerts which could be labeled and that requests for additional data on inerts be restricted to the EPA Administrator's existing authority.

Next to testify was Mr. Gold of the National Pest Control Association. He expressed his organization's support for S. 2346, outlining several provisions of the bill worthy of support. Mr. Gold recommended the expansion of education and training ("updated training requirements") for certified applications and non-certified commercial applicators working under the supervision of certified applicators. These proposals are designed to strengthen the requirements for certification as a commercial applicator, he explained. He called for similarly stringent certification requirements for enforcement personnel and record-keeping adequate to monitor where and by whom quantities of pesticides are used.

On the question of label use, Mr. Gold advocated a provision that would protect applicators who have obeyed the pesticide label and exercised the proper standard of care. He endorsed strong penalties for those who haven't followed standard procedure, though. Mr. Gold decried the tendency of political subdivisions (cities, countries and townships) to exercise regulatory power over pesticides when that is indeed a proper function of the states. Professing no desire to diminish the legitimate regulatory functions of local jurisdictions, he invited localities to press such claims with state regulatory agencies. Material safety data sheets should be provided through state agencies and distributors rather than EPA, Mr. Gold added. He claimed the public's "right to know" would be met more practically and more economically than if the Federal Government had jurisdiction over such matters.

Mr. Borman of Sterling Drug International testified next. He claimed that neither S. 2215 or S. 2346 adequately addressed the regulation of products Sterling makes. He expressed Sterling's vigorous opposition to (1) including antimicrobial and domestic application agents in a reregistration scheme designed for the major agricultural pesticides; (2) reregistration fees; (3) a mandatory system requiring EPA to study and regulate all or more inert ingredients used in pesticides; and (4) liberalizing access to confidential business information. He called for limiting amendments to FIFRA to the major agricultural application pesticides. Sterling's objectives could be realized by amendments regulating domestic application products and antimicrobial base products, such as Lysol brand disinfectant, a Sterling product, Mr. Borman said. This regulation would, of course, be consistent with the inherently less toxic nature of the regulated products and the uniqueness of that portion of the industry, he said.

Mr. Borman claimed the reregistration process has a "disproportionate and unfair" impact on the domestic application/antimicrobial industry. Most of these antimicrobial active ingredients have a very low priority in EPA's current reregistration scheme, he said. Reregistration admission fees for each of these active ingredients are Standard Operating Procedure, Borman explained—regardless of toxicity. This exorbitant fee will deter many businesses from reregistering for economic reasons alone, he said, and may well result in loss of valuable germ-killing products. Mr. Borman said that EPA is currently designing a new reregistration method which takes into account the unique nature of the antimicrobial active ingredients industry. He asked Committee members to accommodate EPA's new flexibility by limiting the proposed amendments to those pesticides given priority in S. 2215.

On the subject of inerts, Mr. Borman aligned Sterling with EPA, the Audubon Society and the Environmental Defense Fund in determining that the only necessary change was to specifically authorize EPA to require identification of a particular inert, after the inert has been determined to pose a hazard. He also registered Sterling's concern with aspects of both S. 2215 and S. 2346 regarding access to confidential and proprietary data ("trade secrets"). Specifically, Mr. Borman objected to new provisions authorizing preregistration access to data on new active ingredients. Given that formula and new active ingredient information is the lifeblood of the domestic application/antimicrobial industry, he said, expanding the universe of persons given access to such information would be harmful. He recommended that access be limited to new active ingredients for food and feed use.

Mr. Russell of Orkin Pest Control testified next about the high efficiency and safety standards of the structural pest control industry. He extolled the safe use of pesticides and cited life expectancy figures to support his claims. As to whether to require certification of technicians (who supervise commercial users of pesticides), Mr. Russell stressed the importance of defining terms. The job description of a service technician is quite different from that of a certified applicator, he said. To require each position to be tested equally would disrupt the delicate balance of performance standards for both—and would adversely affect Orkin's ability to effectively supervise. Mr. Russell called for initial and continuous training of technicians as an alternative to universal certification.

The next panel was introduced by the Chairman. It included: Mr. Robert C. Keeney, Vice President, Government Relations, and Claudia R. Fuquay, Director, Congressional Relations, United Fresh Fruit and Vegetable Association; Mr. Lawrence T. Graham, Executive Vice President, National Food Processors Association (NFPA) and Clausen Ely, Jr., general counsel, NFPA; Benjamin C. Bolusky, Director, Government Affairs, American Association of Nurserymen; and Mr. Peter Hutt, representing the Grocery Manufacturers of America.

Mr. Keeney led off the testimony with an endorsement of S. 2346, based on the bill's recognition of the unique needs of minor crop producers. On reregistration, he expressed the view that pesticide registrations for minor crops should be exempt from fees. Mr. Keeney also cautioned against revoking the tolerances of domestic or imported commodities where there is no health problem because other countries might begin refusing to import U.S. agricultural commodities for the same reason. He expressed the fear that certain labor-related provisions in S. 2215 were weighted unfairly in favor of unionized workers and against employers.

Noting that FIFRA currently prohibits EPA from denying a registration simply because there is another pesticide already registered for use on the same crop against the same pest, Mr. Keeney said that such a prohibition should also apply to the states. Furthermore, he said, states should be prohibited from setting residue tolerances different from those set by EPA. He added that such "independent" tolerances create chaos in interstate transport of agricultural commodities and are a barrier to trade. Noting that his organization's members are farmers, not scientists, Mr. Kenney concluded by stating that users who accurately follow label instructions should not be held liable in any way.

Mr. Graham of the National Food Processors Association testified next, citing the importance of safe and economical raw ingredients to food processors. Mr. Graham criticized the conditional registration and reregistration provisions of S. 2215 as cumbersome, expensive, and unrealistically rigid. He praised the provisions of S. 2346 which establish uniform national pesticide tolerances different from those established by EPA. Mr. Graham further stated that multiple and inconsistent state and local pesticide tolerances are troublesome and disrupt interstate commerce. He also expressed the Food Processors' support for limitations on state-local rights to force reliance on a single or artificially limited number of pesticides. FIFRA, he noted, properly prohibits EPA from denying reregistration of any pesticide merely because another pesticide is available (lack of essentiality). Given the increasing resiliency of pests, Mr. Graham said, alternative pesticides are essential for maximum flexibility in pest management programs.

Mr. Balusky of the American Association of Nurserymen testified next about the importance of safe pesticides in the nursery marketplace. He criticized the Reagan administration's plans to eliminate the IR-4 program, claiming this would greatly diminish the availability of safe pesticides to the nursery industry. Given that nursery production is not a particularly lucrative market for pesticides, he said, it has always been more economically feasible for manufacturers to cater primarily to larger markets. Elimination of IR-4 would leave the nursery industry out in the cold, Balusky claimed, victimized by lack of sufficient approved minor use pesticides. Given that development of new pesticides and access to already registered pesticides depends upon the relative ease or difficulty of introducing those said, Congress should grant a reregistration fee exemption for new pesticides and adding new uses to existing labels. Mr. Balusky called on Congress to "reaffirm its original intent" to preempt local jurisdictions from regulating pesticide use.

Mr. Hutt of GMA testified on what he called "the critical need for legislation to assure national uniformity in the regulation of the levels of pesticide residues found in or on food." This legislation is necessary, he said, because nearly every state has one or more laws regulating the levels of pesticide residues in or on food. Food production, processing and distribution are a truly national undertaking and should be treated that way, Mr. Hutt said.

Mr. William J. Walsh, III, Senior Staff Officer, Commission on Life Sciences, National Research Council, National Academy of Sciences, testified next. Mr. Walsh focused his comments on the relationship of FIFRA to the field of biotechnology (which he predicted would be a $100 billion industry by the year 2000). With regard to biotechnology, he said, EPA has been emphasizing possible costs and benefits to the exclusion of scientifically-based probable costs and scientifically probable benefits. He called for a provision in FIFRA mandating that costs and benefits be determined on the basis of scientifically determined probability and not on the basis of possibility. Important regulatory determinations that are adversely affecting the advancement of biotechnology are being made essentially on the basis of guesswork, he said.

Making such determinations merely on the basis of perceived or imagined possible risks—especially when biotechnology has such wide-ranging effects on medicine and agriculture and pharmaceuticals—is costing the U.S. its leadership in that field, Mr. Walsh said. It is also driving biotechnology research and experimentation underground and to foreign shores, he continued.

Next to testify was Mr. James K. Champion, Riverdale Chemical Company and President, Pesticide Producers Association. Mr. Champion's concerns were primarily business oriented rather than environmental. He called for mandatory industry involvement in the development of data requested under section 3(C) 2(B) of FIFRA to support the continued registration of a currently registered pesticide product. Mr. Champion further asked that the EPA Administrator be allowed to suspend the registration of any registrant who refused to participate in this initiative. He asserted that there should be an equitable method of cost sharing between participants in the data production. Agricultural chemicals should be reasonably priced and not subject to a single supply source, he said.

Robert D. Shockey, Vice President, Pesticide Producers Association, spoke next on the anticompetitive nature of the pesticide industry. Nothing that the top 3 agricultural chemical producers in the world account for 31 percent of world pesticide sales—and that the top 10 account for 66 percent—Mr. Shockey asked Congress to provide a definition of data compensation in FIFRA. After a patent has expired and a new company desires to enter that market, he noted, the new company must make a decision based on all potential costs affecting its business. Within the industry there is a big unknown—data and potential data compensation—that makes business planning impossible. FIFRA provides for data compensation but does not supply a definition of reasonable compensation. The arbitrators have no definition or guidelines upon which to judge "reasonable compensation" for data and their decisions are final. Defining data compensation would guarantee a competitive market in the industry and assure the American consumer of fairly priced pesticide products, he said.

Next to testify was Mr. Donald H. Swan, Group Vice President, Monsanto Agricultural Products Company. He was accompanied by Mr. Larry D. Brady, Vice President, FMC Corporation. Mr. Swan stated his opposition to the Pesticide Producers Association's (PPA) efforts to amend FIFRA's data compensation and arbitration provisions. Companies that expend the time, expense and risk of registering a pesticide should be protected from "follow-ons" who try to benefit from data on the same product without the same costs in resources, he said. Data compensation is a vital protection of the investment necessary to register new pesticides, Mr. Swan claimed. He argued that PPA's "divisive" amendment would discourage innovation.

Chairman Helms next introduced the final panel of witnesses. They were: Maureen Hinkle, Policy Analyst, National Audubon Society, Ellen Haas, Executive Director, Public Voice for Food and Health Policy; and Eric Olson, Counsel, Pollution and Toxic Substances, National Wildlife Federation.

Ms. Hinkle began by stating support for several selected individual provisions of both S. 2215 and S. 2346. She called for tighter standard and higher penalties for civil and criminal violations such as falsifying all or part of registration data submitted to EPA. She strongly criticized state preemption language in S. 2346 regarding sale and use and tolerances. Ms. Hinkle also criticized earlier calls for national uniformtiy of pesticide regulation, claiming that states are acting on their own because of a failure on the national level.

She further suggested that data disclosure not be limited to states, but also extended to certain foreign governments. Ms. Hinkle concluded by urging that inerts (or active ingredients) be required on pesticide labels and that indemnity be struck.

Ms. Haas testified in support of S. 2215, praising the bill for cretating greater public protection from residues of pesticides in the Nation's food supplies. She claimed that only strong government involvement could protect consumers from dangerous, unseen pesticide residues. Because many pesticides have been inadequately tested, she said, consumers are exposed to potential health risks. Ms. Haas praised several specific provisions of S. 2215 for addressing health risks to consumers.

Mr. Olson of the National Wildlife Federation concluded the day's testimony with a call for passage of S. 2215. The bill, he said, will require more complete health and safety tests for all pesticides. He also claimed it would give EPA badly needed substantial new resources to reregister each pesticide. S. 2215 would give EPA new authority to cancel any pesticide registered with invalid or fraudulent data, he said. Mr. Olson further praised the bill for requiring substantial improvements in EPA's regulation of so-called inert ingredients in pesticides and for streamlining unwieldy EPA special review and cancellation procedures. He cited the provision of S. 2215 regulating exportation and importation of pesticides as particularly worthy of support. The legislation's "right to know" provisions will improve public knowledge and participation, he said.

MARKUP

On Wednesday, July 30, 1986, the Committee on Agriculture, Nutrition, and Forestry met to consider markup legislation to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Chairman Helms explained that the purpose of the session was to markup legislative proposals to amend FIFRA in order to produce a workable compromise bill from which all parties could benefit.

Chairman Helms began by defining FIFRA and its basic functions. He described the Act's principal features and briefly summarized the issues at stake in Committee deliberations and markup. He stated his confidence in the bill's equitable treatment of the competing interests involved in crafting the bill. These he described as farmers, consumers, product users, environmentalists, consumer groups, etc. All have a serious stake in the final legislative product, he said, and all should be pleased with the final results.

Senator Lugar proposed that Committee Members tentatively adopt existing staf recomendations, take the House Agriculture Committee's version of FIFRA as the markup vehicle, and then deal with the specific issues. Committee Members approved Senator Lugar's proposal.

The first issue to come up for consideration was a provision entitled: "Effects of Patent Term Restoration on Data Compensation." Staff Counsel explained that the House Commitee's bill included a provision stipulating that if the patent term for a registered pesticide is extended after the date of enactment of said amendments (and pursuant to any congressional amendment) the amount of compensation to be paid in arbitration (for the use of data submitted) would be limited to the fair share of the cost of producing the data—plus a value premium not to exceed that share, as determined in an arbitration. In the case of a registered pesticide no longer under patent, the terms and amount of compensation to be paid by an applicant (intending to file an application for registration for data that was submitted for the pesticide), may be fixed before approval of the registration by arbitration between the original data submitter and the applicant. Staff Counsel explained that the arbitration would be binding on both parties after the registration application is submitted. Each party would share equally in the payment of the arbitrator's fees and expenses and would pay their own attorney's fees plus all subsequent arbitrations involving the same data. Also, Staff Counsel explained, the party seeking to cite the data must pay the fees and expenses of the arbitrator, including the attorney's fees of the original data submitter.

Committee Members engaged in an extended dialogue about this provision. Senator Melcher expressed reservations that the provision would put small companies (whose patent had run out) at a disadvantage. The question was: Is information used to secure a patent public property when that patent expires? If so, the original producers of the data would logically have no just claim to data compensation from companies that use the original research to establish a new and different product. Senator Lugar expressed confidence that these matters could be addressed through a compromise. He subsequently introduced an amendment establishing arbitration to decide the amount of data compensation—and, if the original data producers were not satisfied with the resulting sum, judicial review.

Senator Melcher then addressed himself to the issue of patent life. The standard 17-year patent should begin on the date a given product is marketed with EPA approval, he said, not the date its application is submitted. The reason for this, he said, is that a product's application could be accepted (and its 17-year patent life begun) while subsequent EPA certification could take years—robbing manufacturers of vital patent life. Senator Melcher declared that data compensation "should just be based on a fair share of the actual cost of producing the data, plus an amount no greater than that share." Senator Lugar raised the question of semantics: Just what are legitimate data production costs? And how much money is customarily involved? Mr. Moore of EPA asserted that this was a business issue and therefore beyond the purview of EPA. Senator Melcher said the value of registrations should be essentially zero after 17 years; Senator Lugar argued that the time, work, and resources poured into data production mandates that such data has value—financial and otherwise—for which its producers should be compensated.

Senator Melcher's amendment was defeated, 5-11.

The Lugar amendment provides that the findings and determinations of the arbitrator in an arbitration to determine the amount of compensation to be paid by a subsequent registrant to the original data submitter shall be subject to judicial review in the United States Court of Appeals upon the filing of an action by a party to the arbitration, up to the date said person submits such application. The findings and determinations of the arbitrator will be sustained, if they are supported by substantial evidence, when considered on the record of the arbitration as a whole. The amendment was approved 15-1.

Committee Members began an extended dialogue on an amendment concerning groundwater protection introduced by Senator Hawkins. The amendment provides authority for EPA to require registrants to conduct groundwater monitoring. The Administrator would also be authorized to require this monitoring after receiving information that a pesticide had been detected in groundwater. He would receive the information one of two ways; either it would come from the public, or, registrants would be required to report information based on reliable data to the Administrator and the Governor of the State. The amendment establishes groundwater residue guidance levels. In order to guide EPA and the States in developing appropriate regulatory action, groundwater residue guidance levels would be established. The amendment would require that these levels be established whenever the Administrator registers or reregisters a pesticide that the Administrator determines has the potential to leach into groundwater. In addition, a level would be established if the pesticide had been detected at sampling points in three different geographical areas, the pesticide had been detected in a drinking water well that served a population of over 10,000 people, or a Federal agency or Governor petitioned the EPA to set the level.

Senator Dixon said he thought the amendment should have been addressed earlier on the subcommittee level. Senator Lugar responded by citing previous legislative activity (in the form of the House bill) on groundwater residue guidance levels. Mr. Moore explained that much of the previous work on groundwater matters had been done in House consideration, and that Senator Hawkins' amendment was a resulting by-product. He said the Hawkins amendment was the result of long negotiations between environmentalists, EPA, and industry. Senator Dixon asked that minority staff be allowed to examine the amendment.

The Committee next took up the issue of reregistration fees.

Senator Dixon offered an amendment to require that those registrants who have not marketed an active ingredient, but who subsequently choose to reregister the active ingredient, would pay only 15 percent of the appropriate reregistration fee. Senator Lugar voiced approval of Senator Dixon's approach, and moved that its elements be tentatively adopted as part of the bill. There was no objection. Senator Lugar did express concern about the possibility that there may not be sufficient funds to pay for the program, given the bill's specific timetables for action. Mr. Moore agreed that there was a significant "revenue gap" separating the agency's plans from economic realities. He said it was imperative that this gap be closed. Senator Zorinsky wanted to know some specifics of how projected costs had been determined by EPA. The Committee decided that EPA would submit a report on costs before further action could be taken.

Senator Dixon offered an amendment to provide that a Federal registration for a house and garden pesticide, issued after the date of enactment of these amendments, would serve as a conditional State registration under certain circumstances. Senator Lugar moved that the amendment be tentatively adopted without objection, which it was.

Another amendment, this from Senator Boschwitz, was also tentatively adopted. The amendment would require the small business registrants of pesticide active ingredients that are listed under this section to pay fees, as determined by an apportionment based on their respective market share. Such fees shall be based on a percentage of the average annual gross revenue for each pesticide active ingredient for the last 3 years prior to reregistration, and shall be divided into the following three categories.

The amendment would also define a small business as an unincorporated business, partnership, or a corporation that has an average gross revenue for pesticides for the last three years prior to reregistration that did not exceed $40 million or has 150 or less employees.

With regard to certification and training of applicators (specifically, "worker training"), the Committee adopted a provision that that would require the EPA Administrator to promulgate regulations requiring protection for employees who mix, load, or apply pesticides, as well as agricultural employees who work in pesticide treated areas. Under this scenario, the Administrator would also be required to promulgate regulations that provide for the training of employees who mix, load, or apply pesticides.

On Thursday, August 7, 1986, the markup reconvened. Chairman Helms led off the proceedings by mentioning several aspects of FIFRA reform which remained to be dealt with. Among those were: authority of States to regulate pesticides and State primary enforcement authority in the regulation of pesticide tolerances.

Senator Hawkins began with a summary of her efforts to pass an amendment relating to groundwater protection. She stated that many long hours of negotiation between competing interests had yielded a workable compromise acceptable to all parties. She said the resulting amendment on groundwater protection would have the effect of strengthening the role of the States and clarifying EPA responsibilities should a State fail to act.

Senator Cochran then brought up his amendment relating to State regulation of pesticide use. He explained that the Federal and State governments have the resources and technical expertise to analyze issues related to regulation of pesticides, but most smaller political subdivisions do not. This lack of resources, he said, makes it difficult—if not impossible—for political subdivisions to reach logical decisions supported by evidence and factual information. Senator Cochran further explained that this has not stopped such political subdivisions from trying to impose their own regulation (which may or may not be in line with State/Federal regulations) in the past. His amendment he said, was an effort to define the prerogatives of political subdivisions within given States.

First Senator Lugar, then Senators Leahy, Zorinsky, and Chairman Helms stated their opposition to the Cochran amendment. Their reasons can be summarized as follows: (a) there is a grassroots demand for certain local regulations. The health and safety of citizens sometimes require them; (b) local regulations are a strong bargaining tool for environmentalists, whose support is crucial to the bill's passage; (c) local regulations are not numerous and come about only rarely; (d) there are remedies for aggrieved commercial institutions in the courts. In fact, recent court trends are shifting away from the sovereignty of local ordinances.

Senator Boren introduced an amendment to the Cochran amendment stating that the bill language shall not prohibit a political subdivision from establishing or enforcing notification requirements relating to pesticide use other than a person using a pesticide in or around his own residence. Senator Boren said the amendment would establish a national standard to eliminate multi-state confusion.

Senator Lugar opposed the Boren amendment on the same grounds he had opposed the Cochran amendment itself. He said it explicitly authorizes local jurisdictions to adopt regulations.

After some discussion among Committee Members about the past legislative history of local ordinances and the courts, Senator Cochran withdrew his amendment. Senator Boren again emphasized that he would oppose any report language that implies State government was not authorized to grant power to the municipalities to make notification ordinances. Chairman Helms moved that Committee Members approve the report language, which would be subject to review by each Member prior to reporting the bill. There was no objection.

Senator Cochran then offered an amendment to Section 26A of the bill. His amendment would change the language to provide that the primary enforcement responsibility of a State under the Act would expire on September 1, 1990, unless the Administrator determines that the State has authority to impose appropriate civil and criminal penalties. He explained that his amendment modified the House Committee print by changing the date of January 1, 1989 to September 1, 1990, and by inserting the word "appropriate" to define civil and criminal penalties.

Several Committee Members expressed reservations about Senator Cochran's approach. Senator Leahy said he thought the extension of time was ill-advised, as many States act too slowly as is. Senator Dixon was concerned about confusion in having States usurping Federal prerogative in deciding whether certain State laws were "appropriate." Senator Lugar thought the amendment too "vague." He thought the time extension was acceptable, but asked Senator Cochran to delete the word "appropriate." Senator Cochran agreed to do so. The section of his amendment relating to the expiration date was approved without objection.

Citing the confusing disparity between Federal and State tolerance levels, Chairman Helms offered an amendment providing for national uniformity in the regulation of pesticide residues in or on food (in order to facilitate national production and marketing of food). His amendment also would allow States to establish requirements for a pesticide residue, in or on food, which differ from the uniform requirement in cases of an immediate hazard (until the EPA Administrator acts upon a State's petition for such a differing requirement) and; permit States to petition for an exemption from the national level, if a different requirement is justified by compelling local conditions. Under the amendment, the Federal government could only preempt State tolerances on pesticides registered since April 25, 1985 or on pesticides with a complete database on file at EPA. States would be free to apply their own tolerances on the older pesticides which are generally deemed to be more hazardous. Chairman Helms' amendment was tentatively approved without objection.

Senator Wilson offered an amendment regarding the IR-4 program dealing with pesticide registration for minor use crops. His amendment was designed to guarantee the authority of the Secretary of Agriculture to continue providing support for the IR-4 program. Senator Cochran expressed concern that Committee Members would be directing funding for a program—in a legislative committee—when the Secretary of Agriculture ought to have the same discretion to provide funds for this program as he does to provide funds, or allocate funds that have been appropriated for any other research project that might be important to the safety and health of the consuming public, or the well-being of producers all over the country. The amendment was tentatively approved without objection.

Senator Leahy again declared his opposition to Chairman Helms' amendment on uniform tolerances, asking that the following amendment be tagged on to the end of it: "This section will expire at the conclusion of the 5-year reauthorization period provided by this Act." He said he didn't want to see the plans of State legislatures overridden by undue Federal initiative. Senator Leahy also expressed reservations that the amendment presumed EPA would adequately protect without any separate authority vested in the States. He said the agency moves too slowly, and that his amendment would prevent EPA from dragging its feet. If the States aren't satisfied with EPA's progress under the Helms amendment, he said, it would not be renewed at the end of five years.

Senator Lugar and Chairman Helms expressed general satisfaction with this approach. Senator Leahy's amendment was approved without objection. Senator Harkin then offered an amendment which he said would address the end for according increased attention to potential neurobehavioral hazards of pesticide active and inert ingredients. He explained that under EPA's current pesticide assessment guidelines, only the most damaging pesticides (to the human nervous system) could ever be discovered and controlled. He recommended that Committee Members expand EPA's obligation to ensure that pesticides do not cause neurobiological damage to unsuspecting users in the general public. The amendment was approved without objection.

Staff Counsel then addressed the section of the House Committee print entitled "Tolerance of Agricultural Commodities." It was noted that the Food, Drug, and Cosmetic Act provides general authority for the EPA Administrator to establish tolerances for pesticides on chemicals in or on raw agricultural commodities. Staff Counsel said that the House Committee print would amend the Act to provide that if the registration of a pesticide containing a specific active or inert ingredient (registered for use on a raw commodity) were to be cancelled, voluntarily withdrawn, or suspended due to risks to humans, the EPA Administrator would be required within 60 days to revoke or suspend any tolerance for residues of the pesticide in or on the commodity, or do the same regarding an exemption from a need for such a tolerance. The suspension of a tolerance would be effective so long as the registration of the pesticide is suspended.

Senator Luger noted that the Australians and the Canadians had argued such an intitiative would be a non-tariff barrier, and that American farmers are exporting to Australia and Canada products which possibly contain chemicals banned in other countries. He proposed that Committee Members adopt current law leaving the Administrator the ability to establish tolerance, so we don't get ourselves into another trade war.

Committee Members voted 9–7 in favor of Senator Lugar's motion to adopt current law.

On Thursday, August 13, 1986, the markup reconvened. After Chairman Helms called the Committee to order, Senator Zorinsky offered an amendment concerning patent term restoration. The amendement would modify to a limited extent the court decision in *Roche Products* v. *Bolar Pharmaceutical Co.* by permitting testing of a patented product during specified periods without infringing on the particular pesticide patent. The amendment was approved without objection. Following adoption of the amendment, Chairman Helms' motion to report an original bill was unanimously agreed to.

SECTION-BY-SECTION ANALYSIS

Section 1—Short title

Section 1 provides that the bill may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986" and supplies a table of contents.

Section 2—References

Section 2 states that, except as otherwise specifically provided in the bill, an amendment, or repeal of a section or other provision will be considered to be made to a section or provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("the Act").

TITLE I—PESTICIDE REGISTRATION

Section 101—Preregistration access to data

Section 101(a) would add a new paragraph (9) to section 3(c) of the Act, to provide the public access to data submitted to the Administrator of the Environmental Protection Agency ("the Administrator") to support applications for pesticide registrations.

Subparagraph (A) of new paragraph (9) would require the Administrator to provide public access to health, safety, and environmental data that are submitted or cited in support of an application for the registration of a pesticide containing a new active ingredient or an application for the registration of a pesticide to authorize the initial food use of a previously registered pesticide. The data would be accessible during the period prior to the Administrator's action on the application.

Subparagraph (B) of new paragraph (9) provides that, to obtain access to the preregistration data, a person must send a request for access and the affirmation described below simultaneously to the Administrator and the registration applicant by certified mail, not later than 30 days after the Administrator publishes a notice of the application for registration.

Subparagraph (C) of new paragraph (9) provides that the Administrator must grant the request for access to the data unless, within 15 days after the Administrator's receipt of the request and the required affirmation, the applicant submits an objection asserting that the affirmation is inaccurate and the reasons for the objection. The Administrator must determine whether or not to grant the request within 5 days of receipt of a timely objection. If the request is granted, access must not be permitted until 5 days after the applicant making objection has been notified that access has been granted. If the Administrator denies access to the data, comments on the application for which the data were submitted or cited must be filed within 60 days after the date of the decision denying access.

Subparagraph (D) of new paragraph (9) provides that the preregistration data could be made available only to a person who provides an affirmation, and supporting evidence that the Administrator considers necessary, that the person is not engaged in the production, sale, or distribution of a pesticide, and is neither employed by nor acting directly or indirectly on behalf of a person (of affiliate thereof) engaged in the production, sale, or distribution of a pesticide. The affirmation must identify any business, employer, or other person, if any, on whose behalf the person is requesting the access to data, and state that the person will not intentionally or recklessly violate these provisions. An affiliate of a person is defined as a person who directly or indirectly, through one or more intermediaries, controls or is controlled by or is under common control with the other person. Penalties under section 1001 of title 18 of the United States Code will apply to false statements made in the affirmation.

Subparagraph (E) of new paragraph (9) provides that data supporting an application for registration could be made available to a person only for the purpose of permitting the person to comment to the Administrator on the application. Comments submitted to the Administrator could reasonably quote the data, but no person, including the Administrator, could make the comments public prior to a decision by the Administrator on the application for registration (or after the decision if the application is denied). Except as described below in this paragraph, a person who obtains data under new paragraph (9) (directly or indirectly) could not publish, copy, or transfer the data to any other person for use to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world, or use the data for any purpose before any court or government agency prior to the Administrator's decision to approve the registration (or after the decision, if the application for registration is denied). Preregistration data and comments could be disclosed, consistent with provisions of the Act that protect trade secrets and other information, after registration of the pesticide.

Subparagraph (F) of new paragraph (9) provides that the preregistration data could be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by new paragraph (9), but could not be removed from the office. The Administrator must maintain a record of the persons who inspect the data and a copy of this record must be sent to the data submitter upon request.

Subparagraph (G) of new paragraph 9 provides that, once access to preregistration data is granted, the data could be examined and notes on the data could be taken for use in developing comments on the application for registration. Comments on the application must be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended an additional 30 days by the Administrator for good cause.

Section 101(b) would amend section 3(c)(4) of the Act to require the Administrator to publish notice of an application for the registration of a pesticide not later than 30 days after receipt and provide a 60-day comment period on the application. Section 3(c)(4) currently requires that a notice of application be published "promptly" and provides for a 30-day comment period.

Section 102—Criminal penalties for disclosure of information

Section 102 would amend paragraph (3) of section 14(b) of the Act to provide that any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 of the Act, which would include the new preregistration access to data provisions under section 101, will be finded not more than $25,000, or imprisoned for not more than 3 years, or both. Current law provides a fine of not more than $10,000 and the same maximum prison term.

Section 102 also would add a new provision to paragraph 3 of section 14(b) of the Act providing that any person (including any officer, contractor, or employee of the United States or a State) who is granted preregistration access to data and, in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide, knowingly violates the preregistration access to data provisions under section 101, or knowingly allows data to be made available in violation of those provisions, will be fined not more than $100,000, or imprisoned for not more than 3 years, or both.

Section 103—Conditional registration

Section 103 would amend subparagraphs (B) and (C) of section 3(c)(7) of the Act regarding conditional registrations.

New subparagraph (B) contains provisions, like current law, authorizing the Administrator to conditionally amend the registration of a pesticide to permit additional uses of the pesticide, notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (1) the applicant has submitted or cited the additional data required solely for the proposed additional use; and (2) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment. However, new paragraph (B) will add a third requirement for the conditional registration—that the additional use is in the public interest.

New subparagraph (B), similarly to current law, further provides that no registration of a pesticide could be amended to permit an additional food or feed use of the pesticide during the pendency of any evaluation by the Administrator initiated by a notice stating that the pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under the provisions of the Act (section 3(c)(8)) relating to public interim administrative reviews. The Administrator could amend the registration of a pesticide to add a minor food or feed use, notwithstanding that notice has been issued that the pesticide may meet or exceed the risk criteria, if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is no effective alternative pesticide available that does not meet or exceed the risk criteria.

New subparagraph (B), similarly to current law, would require an applicant seeking an amended registration to submit or cite data that would be required to obtain a registration of a similar pesticide under the Act. If the applicant is unable to submit or cite an item of data because it has not yet been generated, the Administrator could amend the registration of the pesticide under conditions that will require the submission or citation of the data no later than would be allowed for the maintenance of the registration of the similar pesticide under the Act.

New subparagraph (B) contains a provision not in current law that, if data concerning chronic dosing, oncogenicity, reproductive effects, mutagencity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide, and if a reasonably sufficient period of time has elapsed for the generation and submission of the data since the data requirement was first imposed, a conditional amendment to permit an additional use of the pesticide for other than a minor use could not be granted unless the data have been submitted.

New subparagraph (C) would restate current provisions of law to allow the Administrator to conditionally register a pesticide containing an active ingredient not contained in any registered pesticide for a period of time reasonably sufficient for generation and submission of required data that have not been submitted because a period of time reasonably sufficient for the generation of the data has not elapsed since the data requirement was imposed. Any such registration would be subject to (1) the conditions that by the end of the period the Administrator receives the data and the data do not meet or exceed risk criteria associated with human dietary exposure specified in regulations under the provisions of the Act (section 3(c)(8)) relating to public interim administrative reviews; and (2) other conditions that the Administrator may prescribe. A conditional registration could be granted only if the Administrator determines that use of the pesticide during the period will not cause any unreasonable adverse effect on the environment and that use of the pesticide is in the public interest. If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxity, or teratogenicity would be required for registration of the pesticide and a period reasonably sufficent for generation of such data has elapsed since the data requirement was first imposed by the Administrator, then the conditional registration of the pesticide otherwise available under new subparagraph (C) could not be granted unless the data have been submitted.

Section 104—Definition of outstanding data requirement

Section 104 would amend section 2 of the Act by adding a new subsection (ff) to define the term "outstanding data requirement." Under the new definition, the term means a requirement for any study, information, or data necessary to make a final registration determination under the Act that has not been submitted to the Administrator, or if submitted, that the Administrator determines must be resubmitted because it is not valid, complete, or adequate to make a final registration determination. In determining whether a study is valid, complete, or adequate, the Administrator must examine, at a minimum, relevant protocols, documentation of the conduct and anaylsis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

Section 105—Reregistration of registered pesticides

Section 105(a) would add, after section 3 of the Act, a new section 3A to provide for the registration of pesticides.

Subsection (a) of new section 3A would provide a general rule requiring the Administrator to reregister, in accordance with new section 3A, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide that the Administrator had determined after November 1, 1984, and before the effective date of these provisions, that there are no outstanding data requirements and the other requirements for registration under the Act have been met.

Subsection (b) of new section 3A would require the Administrator, not later than one year after the date of enactment of the bill, by order, to issue guidelines to be followed by registrants in summarizing studies, reformatting studies, identifying adverse information, and identifying studies that have been submitted that may not meet the registration requirements of the Act or its regulations. The guidelines would not be subject to judicial review. The Administrator must monitor the progress of registrants in acquiring and submitting data required by section 3A.

New subsection (b) also would establish penalties for certain violations of new section 3A. It would require the Administrator to issue a notice of intent to suspend the registration of a pesticide, in accordance with the procedures provided by section 3(c)(2)(B) of the Act, if the Administrator determines that progress in insufficient to ensure the submission of the data required under a commitment within the time period required under section 3A, or if the registrant fails to submit the data within the time period. A notice of intent to suspend also must be issued if the Administrator determines that tests necessary to fill an outstanding data requirement have not been initiated within one year after the issuance of a notice for additional data under section 3A. If the Administrator determines that progress is insufficient to ensure submission of the data necessary to fill an outstanding data requirement within the prescribed time period or if the required data have not been submitted to the Administrator within the time period, the Administrator would issue a notice of intent to suspend the registration. The Administrator also would issue notice of intent to suspend if a registrant otherwise fails to comply with the provisions of section 3(c)(2)(B, which relate to how registrants are to provide additional data to support an existing registration.

A registrant who submits a false certification under subsection (b) of new section 3A will be considered to have violated the Act and be subject to the civil and criminal penalties under section 14 of the Act.

Subsection (c) of new section 3A provides an outline of the phases under which pesticides will be considered for reregistration under section 3A:

Phase one would include the listing of the active ingredients of pesticides that must be reregistered.

Phase two would require the submission to the Administrator by registrants of (1) notices respecting their intention to seek reregistration; (2) identification of missing an inadequate data; and (3) commitments to replace the missing or inadequate data within the applicable time period.

Phase three would include the submission of certain information supporting the reregistration of the pesticide.

The fourth phase would include an independant initial review by the Administrator of the submission required under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requirements to submit additional data.

Phase five would include the review by the Administrator of data submitted for reregistration and appropriate regulatory action by the Administrator.

Subsection (d) of new section 3A provides for phase one of the reregistration of pesticides. Under these provisions, the Administrator would list the active ingredients of pesticides to be reregistered giving priority to active ingredients (other than active ingredients of pesticides for which registration standards have been issued before the date of enactment of the bill) that, among others: (1) are in use on or in food or feed and may result in postharvest residues; (2) may result in residues of potential toxicological concern in potable groundwater, edible fish, or shellfish; (3) have been determined by the Administrator before the date of enactment of the bill to have significant outstanding data requirements; or (4) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

Subsection (d) would require the Administrator, by order, (1) not later than 70 days after the date of enactment of the bill, to list pesticide active ingredients for which registration standards have been issued; (2) not later than 4 months after date of enactment, to list the first 150 pesticide active ingredients from the priority list described above; (3) not later than 7 months after date of enactment, to list the second 150 of the pesticide active ingredients from the priority list; and (4) not later than 10 months after date of enactment, to list the remainder of the pesticide active ingredients from the priority list. Each of the lists must be published in the Federal Register. The content of the lists would not be subject to judicial review.

The Administrator must notify, by certified mail, registrants of pesticides that contain active ingredients that are published on a list at the time of publication. This notice would specify when registrants must notify the Administrator of their intention to seek or not to seek reregistration.

Subsection (e) of new section 3A, phase two of reregistration, provides, as a general rule, that each registrant of a pesticide that contains an active ingredient listed for reregistration, and not included on the list of pesticide active ingredients with registration standards, must (within the time period described below) submit a notice of intent to seek or not to seek reregistration and any information, commitement, or offer, as described below. (NOTE: Pesticide active ingredients with registration standards would be listed separately and would not be subject to all of the requirements under the preliminary phases of section 3A.)

Specifically, the registrant must notify the Administrator by certified mail whether or not the registrant intends to seek reregistration of the pesticide. If the registrant notifies the Administrator of an intention not to seek reregistration, the Administrator must publish a notice of this fact in the Federal Register. A registrant must notify the Administrator within three months after the publication of the list that includes the active ingredient. The Administrator could extend this period if factors beyond the control of the registrant prevent compliance with the period prescribed.

Subsection (e) provides that each such registrant who submits a notice of intention to seek reregistration must submit, in accordance with regulations issued under the registration provisions of the Act, an idenification of (1) all data required to support registration with respect to the active ingreidient, (2) data previously submitted by the registrant in support of the registration of the pesticide that are inadequate, and (3) data not submitted but required for reregistration.

In addition, the registrant would have to submit either (1) a commitment to replace or submit the inadequate or missing data within a reasonable time determined by the Administrator (but not more than 48 months, unless extended by the Administrator by no more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the prescribed period); or (2) an offer to share in the cost to be incurred by a person who has made a commitment to replace or submit the data and an offer to submit to arbitration under section 3(c)(2)(B) of the Act with regard to sharing in the cost of the data.

Subsection (e) provides that data are inadequate for the above purposes if the data are derived from a study with respect to which the registrant is unable to make a certification that the registrant possesses or has access to the raw data used in or generated by the study. Further, data will be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that the data should be considered to support the registration of the pesticide.

Subsection (e) would also provide sanctions for registrants that do not comply with its requirements. If a registrant does not submit a notice of intention to seek or not seek reregistration not later than 3 months after the listing of the pesticide active ingredient, the Administrator must issue a notice of intent to cancel the registration of the registrant for the pesticide. The notice of intent to cancel must be published in the Federal Register and 60 days allowed for comments. After such 60 days, the Administrator, by order and without further hearing, could cancel the registration or take other action, including extension of the time period, as may be needed to allow the reregistration of the pesticide by another person.

If no registrant of a pesticide containing an active ingredient listed for reregistration notifies the Administrator that the registrant intends to seek reregistration of any pesticide containing that active ingredient, or if no registrant complies, as required under phase two, with the requirements for identification of missing had inadequate data and submission of a commitment to replace the missing or inadequate data within the applicable time period, or if the required reregistration fee has not been paid, then the Administrator must publish in the Federal Register a notice of intent to remove the active ingredient from the reregistration list and a notice of intent to cancel the registrations of all pesticides containing the active ingredient. The Administrator must provide 60 days for comments on the notice. After the 60-day comment period, the Administrator, by order, could cancel any of the registrations without a hearing. However, the Administrator could not cancel a registration under this provision if, during the comment period, a person acquires the registrant's rights in the registration and furnishes a notice of intent to reregister the pesticide, and not later than 120 days after publication of the notice of intent to cancel, the person complies with the other requirements of phase two and pays the reregistration fee.

Subsection (f) of new section 3A provides for phase three of reregistration. Each registrant who has submitted, under phase two, a notice of intent to seek the reregistration of a pesticide active ingredient listed for reregistration, not including pesticide active ingredients with registration standards, must submit within 12 months after listing and in accordance with the guidelines issued by the Administrator—

> (1) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing the active ingredient and considered by the registrant to be adequate to meet the requirement of the registration provisions of the Act and its regulations, and a certification that the registrant possesses or has access to the raw data used in or generated by the studies;
>
> (2) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing the active ingredient that may not comply with the registration provisions of the Act and its regulations, but that the registrant asserts should be deemed to comply with the regulations, and a certification that the registrant possesses or has access to the raw data used in or generated by the studies;
>
> (3) a reformat of the data from each study summarized as described above concerning chronic dosing, oncogenicity, repro-

ductive effects, mutagenicity, neurotoxicity, or teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(4) where data that are to be so reformatted are not required for the active ingredient by the regulations issued under the registraiton provisions of the Act, a reformat of acute and subchronic dosing data submitted by the registrant before January 1, 1982, that the registrant considers to be adequate to meet the requirements of the registration provisions of the Act an its regulations;

(5) an identification of data that are required to be submitted to the Administrator as indicating an adverse effect of the pesticide under proposed new section 6(g)(4) of the Act, to be added by section 305 of the bill;

(6) an identification of any other information available that in the registrant's view supports the registration;

(7) either a commitment to submit data to fill each outstanding data requirement identified by the registrant, within a reasonable period of time determined by the Administrator but not more than 48 months (unless the Administrator extends this period by not more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the 48-month period), or an offer to share in the cost of developing the data to be incurred by a person who has made a commitment to submit the data and an offer to submit to arbitration under section 3(c)(2)(B) of the Act with regard to cost sharing; and

(8) evidence of compliance with the data compensation provisions of the Act and its regulations with regard to previous submitted data as if the registrant were now seeking the original registration of the pesticide.

Subsection (e) provides sanctions for registrants that fail to comply with the requirements of phase three. If the registrant of a pesticide fails to submit the information required under phase three within the prescribed time period, the Administrator, by order and without hearing, must cancel the registration of the pesticide.

If the registrant submits the phase three information within the time period prescribed but the information does not conform to the guidelines for submissions established by the Administrator, the Administrator must determine whether the registrant made a good-faith attempt to conform to the guidelines. If the Administrator determines that the registrant make a good-faith attempt to conform to the guidelines, the registrant will be provided a reasonable time to make necessary changes or corrections. If the Administrator determines that the registrant did not make a good-faith attempt to conform, a notice of intent to cancel the registration would be issued, and sent to the registrant by certified mail. The registration will be canceled without a hearing of further notice 30 days after the registrant receives the notice unless a hearing is requested by the registrant. A hearing would be conducted under the hearing provision of section 6(d) of the Act, except that the only matter for resolution at the hearing would be whether the registrant made a good-faith attempt to conform its submission to the guidelines. The hearing must be held and a determination made within 75 days after the receipt of the request for a hearing.

Subsection (g) of new section 3A would provide for phase four of reregistration. The Administrator must review the submissions of all registrants made under phases two and three of reregistration with regard to an active ingredient to determine if all data concerning that ingredient that are missing or inadequate were identified. The Administrator could require registrants to submit complete copies of studies summarized under phase three.

Subsection (g) also would require the Administrator to independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient listed under phase one that is contained in a pesticide to be reregistered (other than any pesticide active ingredient for which registration standards have been issued). The Administrator, at the same time, must issue notice under section 3(c)(2)(B) of the Act to require the submission of additional data necessary to meet the outstanding data requirements. The Administrator must take the actions required under phase four, in the case of a pesticide containing an active ingredient without a registration standard, listed under phase one in the first group of 150, not later than 18 months after the date of the listing. For a pesticide containing an active ingredient without a registration standard, listed under phase one in the second group of 150, the Administrator must take the actions required under phase four not later than 24 months after the date of listing. In the case of a pesticide containing an active ingredient without a registration standard, listed under phase one in the last group of active ingredients to be reregistered, the Administrator must take the actions required under phase four not later than 33 months after the date of the listing.

New subsection (g) would provide that, if the Administrator issues a notice to a registrant under phase four for the submission of additional data, the registrant must submit the data within a reasonable period of time determined by the Administrator (but not to exceed 48 months after issuance of the notice). The Administrator, on application of a registrant, could extend this period by no more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the prescribed period.

Subsection (h) of new section 3A would provide for phase five of reregistration. Under subsection (h), the Administrator must conduct a thorough examination of all data submitted under the reregistration provisions for each active ingredient, and all other available data found by the Administrator to be relevant. Within one year after the submission of all data concerning an active ingredient submitted under subsection (g), the Administrator must determine whether pesticides containing the active ingredient are eligible for registration. For extraordinary circumstances, the Administrator could extend such period for up to one additional year.

Before reregistering a pesticide, the Administrator must obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B). The Administrator must require that the product-specific data be submitted not later than eight months after it is determined that a pesticide is eligible for reregistration, unless the

Administrator determines that a longer period is required for generation of the data. The Administrator then must review such data within 90 days after its submission.

Under subsection (h), after conducting the required reviews, the Administrator must determine whether to reregister a pesticide by determining if the pesticide meets the registration requirements of the Act. If the Administrator determines that a pesticide is eligible to be reregistered, then it must be reregistered within six months following the date all required product-specific data were submitted for the pesticide. If after conducting the required reviews the Administrator determines that a pesticide should not be reregistered, the Administrator must take appropriate regulatory action.

Subsection (i) of new section 3A contains provisions for compensation of data submitters under section 3A for use of such data. Subsection (i) provides that the existing data compensation provisions of section 3 of the Act will apply to data submitted by a registrant under phases two through five that are used to support the application for registration of another person under section 3. In determining the amount of compensation, fees paid by the registrant for reregistration must be taken into account.

Subsection (j) of new section 3A would provide for the payment of reregistration fees. This subsection provides that registrants of pesticides that contain an active ingredient listed under phase one (other than any active ingredient that has been the subject to a registration standard) that is an active ingredient of any pesticide registered for a major use on food or feed must collectively pay an initial fee of $50,000 on submission of the information under phase two. Registrants of the above described pesticides must collectively pay a final fee of $100,000 on submission of data or other information concerning the active ingredient under phase three.

Subsection (j) provides that registrants of pesticides that contain an active ingredient listed under phase one for which a registration standard *has* been issued and that is contained in any pesticide registered for a major use on food or feed must collectively pay a fee of $100,000 at a time prescribed by the Administrator.

Subsection (j) provides that registrants of pesticides containing an active ingredient listed under phase one for reregistration (not including those active ingredients with registration standards) that is not contained in any pesticide registered for a major use on food or feed must collectively pay fees in an amount determined by the Administrator. The fees could not be less than one-half of, nor greater than the above-described fees for pesticides registered for a major use on food or feed. Such fees would be paid at the same time as the above-described fees.

Registrants of pesticides, listed under phase one, containing an active ingredient for which a registration standard *has* been issued and that is not contained in any pesticide registered for a major use on food or feed must collectively pay a fee of not more than $100,000 and not less than $50,000 at a time prescribed by the Administrator.

Under subsection (j), in the case of an active ingredient of a pesticide that is registered solely for an agricultural or nonagricultural minor use or in the case of a pesticide the value or volume of use of which is small, the Administrator, on application, could reduce or waive the fees described above. In the case of a antimicrobial active ingredient for which the production level does not exceed 1,000,000 pounds per year, the Administrator, on application, could reduce or waive the fees described above.

In the case of a small business registrant of a pesticide, the registrant, after apportionment, must pay a fee for reregistration that does not exceed the following amounts: if during the 3-year period prior to reregistration the average annual gross revenue of the registrant from pesticides containing such active ingredient is less than $5,000,000, the registrant must pay 0.5 percent of the revenue; if the annual gross revenue is between $5,000,000 and $10,000,000, the registrant must pay 1 percent of the revenue; or if the annual gross revenue is $10,000,000 or more, the registrant must pay 1.5 percent of the revenue but not more than $150,000. A small business registrant is defined as a corporation, partnership, or unincorporated business that has 150 or fewer employees, and for the last 3 years before the application for a reduction or waiver had an average annual gross revenue that did not exceed $40,000,000.

Subsection (j) provides that, on payment of fees in accordance with the above described provisions, the Administrator could not levy any other fees for reregistration with respect to that active ingredient.

If two or more registrants are required to pay a fee with respect to a particular active ingredient, the fees for the active ingredient must be apportioned among the registrants on the basis of the market shares of domestic sales of the active ingredient for the preceding three calendar years except that small business registrants that produce the active ingredient must pay fees as described above and registrants who have not marketed the active ingredient during the 3 calendar years but who choose to reregister the active ingredient must pay 15 percent of the fees. The Administrator, by order, could require a registrant to submit a report to allow the Administrator to apportion fees under this provision.

If any required apportionment report is not submitted by a registrant after receiving notice, or if any fee is not paid on time, the Administrator, by order and without hearing, could cancel each registration held by the registrant of a pesticide containing the active ingredient involved. The Administrator then must reapportion the fee among the remaining registrants and notify the registrants that they are required to pay any unpaid balance of the fee within 30 days after receipt of the notice.

Subsection (k) of new section 3A provides that the requirements of phases two, three, and four and the fee requirements of section 3A will not apply to any person who is the registrant of a pesticide to the extent that, under the exemption provided under section 3(c)(2)(D) of the Act, the person would not be required to submit or cite data to obtain an initial registration of the pesticide under section 3.

Subsection (l) of new section 3A would establish in the Treasury of the United States a reregistration fund. Reregistration fees collected by the Administrator would be deposited into the fund and be available to the Administrator, without fiscal year limitation, to carry out the reregistration provisions. Money in the fund not currently needed to carry out reregistration activities could be maintained on hand or on deposit, invested in obligations of, or guaranteed by, the United States, or invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds. The Administrator would be required to provide an annual accounting of the fees collected and disbursed from the fund and take all steps necessary to ensure that the expenditure of the funds are used only to carry out the reregistration provisions.

Subsection (m) of new section 3A provides that any failure of the Administrator to take any action required under the reregistration provisions of section 3A will be subject to judicial review under section 16(b) of the Act.

Section 105(b) would make a technical amendment to repeal subsection (g) of section 3 of the Act (which provides only that the Administrator must accomplish reregistration in the most expeditious manner possible, giving priority to pesticides that leave postharvest residues on crops).

Section 105(c) would amend section 2 of the Act by adding a new subsection (gg) to define the term "antimicrobial". Under the new definition, the term means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air;

(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

(3) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or in water or air;

(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or

(5) fungicides or fungistats.

Section 105(c) also would amend section 2(u) of the Act to include in the definition of the term "pesticide" any substance or mixture of substances intended for any of the antimicrobial purposes described in clauses (1) through (5) of the preceding paragraph.

Section 106—Administrator's authority to require data on inert ingredients

Section 106(a) would amend section 3(c)(2)(A) of the Act to provide that, if the Administrator requires additional information about an inert ingredient to support the registration of a pesticide, a sufficient time must be permitted for registrants to obtain the information.

Section 106(b) would amend section 3 of the Act by adding a new subsection (g) to direct the Administrator to establish a priority list of: (1) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under the Act; (2) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect, and that have significant use in pesticides or to which there is significant exposure from pesticides; and (3) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, if the pesticide is one to which there is significant exposure. In establishing the priority list, the Administrator must take into account the differences in concept, usage, and environmental risks between various classes of pesticides; and data for evaluating the risks between agricultural and nonagricultural pesticides.

The priority list must be published by the Administrator not later than 90 days after the effective date of the bill. Revisions to the list must be published annually. The priority list, any inert ingredient's inclusion on or exclusion from the list, or any revision to the list would not be subject to judicial review.

The priority list must consist of not less than 50 inert ingredients unless the Administrator determines that there are fewer than 50 inert ingredients that meet the requirements for inclusion on the list. The list may not exceed 75 inert ingredients.

New subsection (g) also would require the Administrator to determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list described above. Section 106(b) would require the Administrator to demand each registrant of the pesticide, or manufacturer or processor of the inert ingredient under the Toxic Substances Control Act, to submit the data. The data must be submitted within a reasonable time but not later than four years after the request, unless the Administrator extends the period by not more than two years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the data. Data requirements imposed, or a decision not to require data for an inert ingredient, would be subject to judicial review under procedures provided in section 16(b) of the Act.

On receipt of additional data the Administrator must, within one year, evaluate the data and take appropriate steps to prevent unreasonable adverse effects on the environment caused by pesticides that contain the inert ingredient. Under exceptional circumstances, the Administrator could extend the evaluation period by not more than one year.

New subsection (g) states that it should not be construed to affect any other authority of the Administrator to regulate impurities, contaminants, degradants, or other ingredients of pesticides that have been deliberately added; to regulate any deliberately added inert ingredient that has not previously been used in a pesticide, or a significant new use of the inert ingredient in a pesticide; to require the submission of short-term environmental fate or residue studies for deliberately added inert ingredients; or to require the submission of revised formula statements under section 3(c)(2)(B) of the Act.

The Committee intends that subsection (g) be construed in a manner that does not affect the authority of the Administrator to regulate ingredients that are not deliberately added to pesticides. More specifically, it is the Committee's intent that the Administrator remain free to regulate ingredients that are not deliberately added under whatever authorities are available. Thus, the presence of any particular ingredient on the priority list established under subsection (g) should not be a basis for the Administrator not proceeding under other authorities. By the same token, however, the Committee intends that the Administrator exercise sound judgment in deciding whether to proceed under this subsection or under other existing authorities. In this fashion, the Committee expects the Administrator to weigh the regulatory options available and choose those most consistent with the objectives of the bill while accommodating the reasonable concerns of registrants about unnecessarily duplicative approaches.

Section 106(b) also will amend section 3(c)(1)(D) of the Act to clarify that data submitted in support of the safety of an inert ingredient would be subject to the data compensation provisions of the Act (as limited by the exclusive use provisions of such section) for the 15-year period following the date the data were originally submitted.

Section 107—Definition of ingredient statement

Section 107 would amend section 2(n) of the Act to redefine the term "ingredient statement" to mean a statement that contains (1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients in the pesticide; (2) the name of each inert ingredient in a pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the toxicity, use pattern, and concentration level of the inert ingredient in the pesticide; (3) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic; (4) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented; and (5) the name of any inert ingredient for which the Administrator has required additional data under new subsection (g)(5) of section 3 because the inert ingredient is listed in new subsection (g)(1), as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under the Act.

NOTE.—The definition, under current law, consists only of the items described in clauses (1) and (3) of the preceding sentence.

Section 108—Disclosure of inert ingredients

Section 108 would amend section 10(d) of the Act to allow the disclosure of information on inert ingredients in ingredient statements.

Section 109—Compensation for data on inert ingredients

Section 109 would amend the provisions of section 3(c)(2)(D) of the Act (which contains the so-called "formulator exemption") to add a new requirement that no applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person to formulate the pesticide will be required to offer to pay reasonable compensation otherwise required by the Act for a study concerning the inert ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.

TITLE II—INFORMATION DISCLOSURE

Section 201—Public right to know

Section 201(a) would amend section 7 of the Act by adding a new subsection (e) to require any producer operating a pesticide production establishment in any State to prepare or obtain a fact sheet for each active ingredient manufactured or used at the establishment. The producer must maintain copies of the fact sheet at the establishment and furnish a copy to any person on request.

Each fact sheet must contain the chemical name, each common name, and any trade name of the active ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient. Fact sheets must be revised as often as is necessary to reflect current information about the active ingredient. The Administrator could require a fact sheet to be amended to provide accurate and clear information to the public.

Each producer must furnish to the Administrator annually, in accordance with regulations published by the Administrator, a report that includes the name of each ingredient for which a fact sheet is required that is manufactured or used at each establishment operated by the producer, and the location of each establishment where the ingredient is manufactured or used by the producer, and a copy of the most current fact sheet. Fact sheets and annual reports must be made available to the public.

Section 201(b) would amend section 7(d) of the Act to provide that information about pesticide production locations submitted to the Administrator is not to be considered confidential or subject to the trade secrets provisions of the Act.

Section 202—Data disclosure to States

Section 202 would amend section 10 of the Act by adding a new subsection (h) to allow the Administrator to disclose to a State any data or information acquired under the Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided under the Act (see paragraph (1) of new subsection (h).

New subsection (h), in paragraph (3), would require the Administrator to disclose such data or information, to any State based on such assurances if the State makes further assurance, and the Secretary determines, that the law of the State allows the submitter to recover just compensation in a civil action against the State for losses that result from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or 10 of the Act.

Paragraph (2) of new subsection (h) provides that, for purposes of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code, the disclosure or use by a State of data or information, provided by the Administrator under paragraph (1), in a manner inconsistent with section 3 or 10 of the Act must be considered a taking of property and the act of the State will be considered an act of the United States.

TITLE III—REVIEW AND CANCELLATION

Section 301—Public interim administrative review

Section 301(a) would amend paragraph (8) of section 3(c) of the Act, which deals with public interim administrative reviews.

Subparagraph (A) of new paragraph (8) provides that, in general, a public interim administrative review to determine whether the use of a pesticide (including a category of pesticides) may pose unreasonable adverse effects to humans or the environment must be conducted in accordance with new paragraph (8).

Subparagraph (B) of new paragraph (8) would require the Administrator to set forth, in published regulations, the criteria for initiating a public interim administrative review. The criteria must be based on levels of risk and could include consideration of currently available exposure data. The absence of exposure data must not delay or preclude initiation of a public interim administrative review. The Administrator could decline to initiate a review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

Subparagraph (C) of new paragraph (8) would restate existing law (current paragraph (8)), which provides that the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of the pesticide under the Act unless the public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

Subparagraph (D) of new paragraph (8) provides that, on receipt of information about a pesticide demonstrating that the criteria for initiating a public interim administrative review have been met, the Administrator must immediately notify all registrants of the pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met. Not later than 30 days after receipt of the notice, a registrant could respond to the notice. Not later than 60 days after the Administrator provides a notice, the Administrator must determine whether a public interim administrative review of the pesticide will be initiated.

Subparagraph (E) of new paragraph (8) would require that, if the Administrator intends to initiate a public interim administrative review of a pesticide registered for agricultural uses, the Administrator notify the Secretary of Agriculture of the intention to initiate the review and the reasons for the review.

Subparagraph (F) of new paragraph (8) would establish procedures for the public interim administrative review. Any public interim administrative review must be initiated and conducted in accordance with regulations published by the Administrator. The regulations must provide that a public interim administrative review include a notice of initiation of the review and opportunity for public comment on the notice, a notice of the Administrator's preliminary determination and opportunity for public comment thereon, and a notice of final determination. The regulations could authorize the Administrator to combine or forgo any of the above notices. Any proposed determination of the Administrator must be submitted to the Scientific Advisory Panel at its next scheduled meeting for comment solely on relevant scientific issues. The public would be allowed to submit comments to the Scientific Advisory Panel on the scientific issues.

Under subparagraph (F), the notice of the initiation of a public interim administrative review or the notice of preliminary determination must state the basis for the review or determination and include a request for any additional data needed, and a bibliography of all scientific data and studies, and expert analyses, concerning the risks or benefits of the pesticide that are under review. Information in the bibliography must be made available to the public consistent with the trade secrets provisions of the Act. The Administrator must determine, to the extent feasible, before the initiation of the review which data in the bibliography could be disclosed to the public under the Act. If the Administrator receives additional data concerning the risk or benefits, the bibliography must be revised within 30 days and made available to the public.

Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments could be submitted on the review or determination. Any person who submits comments must disclose to the Administrator all scientific data and studies, and analyses, in the person's possession concerning the risks or benefits of the pesticide that are under review that were not included in the bibliography in the notice. New scientific data, studies, and expert analyses of the data must be disclosed to the Administrator by such person within 30 days after he receives them.

Subparagraph (F) would require the Administrator to decide, not later than 18 months after the initiation of a review, which regulatory action (if any) to take and publish the decision.

The time limits specified for the review could not be extended, except in exceptional circumstances in which (1) additional data critical to a fair and accurate determination of risks posed by the pesticide are required; (2) the extension is for a period limited to the time required to obtain the data on an expedited basis and in no event to exceed one year; and (3) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for the data at that time.

Subparagraph (G) of new paragraph (8) would allow any person to seek judicial review under section 16(a) of the Act for failure of the Administrator to act within a required time period.

Section 301(b) would make a conforming amendment to section 25(d) of the Act, regarding submissions under new paragraph (8) to the Scientific Advisory Panel.

Section 301(c) provides that the amendments made to section 3(c)(8) of the Act will apply only to public interim administrative reviews initiated after January 1, 1987.

Section 302—Proceedings under section 6

Section 302 would amend section 6 of the Act (administrative review and cancellation) by redesignating subsection (f) as subsection (i) and adding a new subsection (f) to provide special procedures for public hearings resulting from a public interim administrative review.

Paragraph (1) of subsection (f) provides that the special rules described below will govern a hearing that results from the Administrator's final determination in a public interim administrative review that (1) is initiated after January 1, 1987, (2) includes an opportunity for comment on a notice of preliminary determination, and (3) for which the time between the first public notice for the review and the close of the last comment period for the review is not less than 180 days. Otherwise, the provisions of subsection (d) of section 6 (as revised by section 304 of the bill) will govern such hearings.

Paragraph (2) of new subsection (f) provides that any person who is adversely affected by a decision of the Administrator respecting a pesticide, including a person without an economic interest, following a public interim administrative review could request, or intervene in, a hearing (in the manner provided by subsection (b)(2)(B) of section 6 (as added by section 303 of the bill)) within 30 days after the decision. The party would have to identify with particularity the disputed findings or conclusions of the decision and include a complete statement of the reasons and factual basis for the request. A person could request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with the procedural provisions of section 3(c)(8) governing public interim administrative reviews (as added by section 301(a) of the bill).

Paragraph (3) of new subsection (f) provides for certain procedures to be followed at a hearing following a public interim administrative review. Under these provisions, at the request of a party, the administrative law judge conducting the hearing could receive into evidence portions of the review record and other evidence that the party demonstrates are relevant and material to the disputed issues and are not unduly repetitious, if a competent witness is made available to be cross-examined on all matters relating to the evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the review proceeding by the exercise of due diligence would not be admissible at the hearing. The right of other parties to confront and cross-examine witnesses would be preserved with respect to material issues of adjudicative fact, so long as the cross-examination is not unduly repetitious.

Paragraph (3) also provides that, not later than 120 days after the administrative law judge is appointed, prehearing matters must be completed and the hearing begun. The administrative law judge could establish a schedule for prehearing matters, including prehearing discovery and motions, and must ensure that the hearing schedule is met. The administrative law judge must issue appropriate orders for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, breifing, and decision. Further discovery would be permitted after such 120-day period only on a determination by the administrative law judge that (1) the discovery would not in any way unreasonably delay the proceeding, (2) the information to be obtained is not otherwise obtainable, and (3) the information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

Paragraph (3) states that any challenge to the authority to issue, or the procedural correctness of the issuance of, any notice of intent to cancel or change classification, or to any request for a hearing or motion to intervene, must be filed with the administrative law judge before the evidentiary phase of the hearing. Not later than 30 days before the hearing begins, the parties must exchange witness lists, a brief narrative summary of expected testimony, and a list of all documents and exhibits expected to be introduced at the hearing. Thereafter, witnesses, documents, or exhibits could be added and narrative summaries of expected testimony amended by motion.

If new studies become available that were not available during the public interim administrative review, the administrative law judge, on request of any party and if necessary, could submit the studies to the Scientific Advisory Panel for supplemental comment on an expedited basis (and under time limits set by the judge).

The administrative law judge must schedule the presentation and examination of witnesses so that the presentation of evidence is completed with 60 days after the commencement of the hearing, except that this schedule is not to prejudice the right of a party to present evidence. The person who requested a hearing on an issue will have the burden of going forward to present an affirmative case and have the burden of proof on that issue.

Under paragraph (3), a hearing must be completed and the Administrator mut make a final decision within 300 days after the issuance of the notice of the final determination (under the public interim administrative review procedure) that gave rise to the hearing. This overall time limit could not be extended, except in exceptional circumstances in which it is essential for a fair and accurate determination of pivotal facts central to the proceeding, and in no event by more than an additional 180 days. Other time limits under paragraph (3) could be extended for good cause. Failure to complete a hearing and make a final decision within 300 days will be grounds for a civil action in a district court of the United States to seek an order to establish a schedule requiring the prompt completion of the hearing, but will not be grounds for termination of the hearing or for making a final decision respecting the pesticide.

Section 303—Cancellation and change in classification or labels

Section 303 would amend subsection (b) of section 6 of the Act, which contains procedures for cancellation and change in classification (under current law, it contains no specific provisions relating to label changes).

Paragraph (1) of new subsection (b) would restate existing law that if it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator can issue a notice of intent (1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the action of the Administrator; or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed. The notice of the intent of the Administrator must be sent to each registrant of the pesticide and be made public. In determining whether to issue the notice, the Administrator must include among those factors to be taken into account the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

Not later than 60 days before sending the notice to a registrant or its being made public, whichever occurs first, the Administrator must provide the Secretary of Agriculture with a copy of the proposed notice and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture must provide comments on the notice and analysis to the Administrator within 30 days after receipt. If the Secretary of Agriculture provides comments in writing within 30 days, the Administrator must publish in the Federal Register (with the notice) the comments of the Secretary and the response by the Administrator. If the Secretary of Agriculture does not provide comments in writing within 30 days, the Administrator can notify the registrant and make public the notice at any time after the 30-day period. The time requirements can be waived or modified to the extent agreed upon by the Administrator and the Secretary of Agriculture.

If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator can waive the requirement of notice to the Secretary of Agriculture and submission to the Scientific Advisory Panel and proceed in accordance with the suspension provisions of subsection (c) of section 6.

Paragraph (2) of new subsection (b) would restate and add to existing law to provide that the action proposed in the notice of intent will become final and effective at the end of 30 days after receipt by the registrant or publication, which ever occurs later, unless within that time the registrant makes the necessary corrections, if possible, or a request for a hearing is made by a person adversely affected by the notice.

New requirements would be imposed if a request for a hearing is made. Specifically, the request would have to identify with particularly the findings and conclusions of the decision of the Administrator that are disputed, and include a complete statement of the reasons and factual basis that support the request for a hearing. Any party to the proceeding would be allowed to identify findings and conclusions in dispute.

As under existing law, if a hearing is held pursuant to a request, or the determination of the Administrator to hold a hearing, a decision pertaining to registration or classification issued after completion of the hearing will be final.

Under a new provision, before convening a hearing on the request of a person without an economic interest in the pesticide, the Administrator would have to determine that the request presents a substantial issue of fact pertaining to whether the pesticide poses an unreasonable risk to man or the environment. Only if the Administrator made a determination that the request presents such an issue would the Administrator be required to convene a hearing.

Paragraph (3) of new subsection (b) would restate existing law that in taking any action to issue a notice of intent to cancel a registration, change its classification, or hold a hearing to determine whether or not the registration should be cancelled or its classification changed, the Administrator must consider (1) restricting uses of the pesticide as an alternative to cancellation and fully explain the reasons for the restriction; and (2) the impact of the action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of the impact.

Paragraph (4) of new subsection (b) contains new provisions for pesticide label changes that could be required by the Administrator through informal rulemaking. The Administrator could require label changes, under these provisions, by informal rulemaking, unless the proposed changes are equivalent to a cancellation of use, render the product unmarketable, or otherwise have a major economic impact on persons affected by the changes. If the Administrator is so precluded from making the proposed label changes, the Administrator could require the changes only through another proceeding authorized by the Act.

Under paragraph (4), the Administrator could notify the registrant of the proposed label change and provide for comments by the registrant during a 30-day period beginning on the date of the registrant's receipt of the notice. If the registrant notifies the Administrator that the registrant does not object to the proposed label change, then the change will take effect as prescribed by the Administrator. If the registrant does not submit comments to the Administrator in the 30-day period, the Administrator must notify the registrant that, if the registrant does not submit comments within 30 days after the second notice, the registration will be cancelled without a hearing or further notice. If the registrant objects, the Administrator can proceed further only as described in the preceding paragraph.

Paragraph (4) also provides that, if a regulation is promulgated that requires a label change, the Administrator must notify each registrant of the pesticide subject to the regulation and provide a 30-day period for each registrant to apply for an amendment to the registration to comply with the regulation. If a registrant does not apply for an amendment within the 30-day period, the Administrator must issue a notice of intent to cancel the registration in accordance with paragraph (2). Such notice of intent to cancel will be deemed to have been issued under paragraph (1), described above, for purposes of the paragraph (2) hearing procedures.

A registrant or user of a pesticide subject to the regulation could request a hearing on the regulation in accordance with paragraph

(2). The scope of the hearing would be limited to (1) whether the pesticide complies with the regulation; (20 whether the regulation by its terms is applicable to the pesticide; and (3) whether, because of significant information that was not (and could not reasonably have been) presented in the rulemaking proceeding, it would be unreasonable to require the pesticide to comply with the regulation.

Paragraph (4) would require a court, in an action for review of the regulation under section 16(e) of the Act, on request, to postpone the effective date of the regulation until completion of the review action if the petitioners shows a likelihood of success on the merits in the action, and that implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner. However, the court could not postpone the effective date of the regulation if the Administrator shows that failure to implement the regulation would cause a risk of substantial harm to health or the environment.

Section 304—Public hearings and scientific review

Section 304 would amend section 6(d) of the Act, which contains procedures for the conduct of hearings initiated under section 6(b) of the Act, to delete provisions relating to referrals of questions of scientific fact to a committee of the National Academy of Sciences.

Section 304 also would amend section 6(d) of the Act to provide that, as soon as practicable after completion of the hearing, but not later than 18 months after the issuance of the notice that gave rise to the hearing, the Administrator must evaluate the data and reports before him and (1) issue an order revoking the section 6(b) notice of intent, or (2) issue an order either cancelling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. (Note: Under current law, the Administrator has only 90 days to so act.) Also, a new provision would be added to section 6(d) to permit the time period to be extended by the Administrator under extraordinary circumstances for not more than one year.

Section 305—Administrative changes

Section 305(a) would amend section 6 of the Act to provide certain general provisions in a new subsection (g). Under new subsection (g), a registrant, at any time, could request that any of its pesticide registrations be cancelled or amended to delete one or more uses. Before acting on the request, the Administrator would be required to publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator could approve the request.

New subsection (g) also would specify that a notice of denial of registration, notice of intent to cancel, notice of suspension, or notice of intent to suspend issued under the Act, certain other notices under the registration provisions of new section 3A (to be added by section 105(a) of the bill), and a second notice of a label change under paragraph (4) of section 6(b) (to be added by section 303) must be published in the Federal Register and sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notices is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice after making reasonable efforts to do so, the notice will be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

New subsection (g) essentially would restate existing law (now contained in subsection (a) of section (6) with respect to existing stocks of cancelled pesticides. It provides that the Administrator could permit the continued use, the continued distribution or sale, or both, of existing stocks of a pesticide whose registration is cancelled under any provision of the Act to the extent, under conditions, during periods, and for uses as the Administrator may specify if the Administrator determines that the distribution, sale, or use is not inconsistent with the purposes of the Act and will not cause unreasonable adverse effects on the environment.

New subsection (g) would restate and clarify existing law (now contained in section 6(a)(2)) that, if at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the information must be submitted to the Administrator. The term "information" is defined to include factual information and expert opinion regarding risks or benefits. (See also the analyses of section 305(b)(2) below.)

Section 305(b)(1) would amend section 3(c)(6) of the Act to provide that if the Administrator issues a notice of the denial of registration, a request for a hearing under section 6 of the Act (as authorized under current law) must be made within 30 days after the receipt of the notification. The Administrator would be authorized to issue regulations governing the right to a hearing with respect to the denial of any application for the registration of a product containing a ingredient that was cancelled under section 6. Under the regulations, due weight must be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings. The notice requirements of new subsection (g) of section 6 (to be added by section 305(a)) regarding publication of a notice of the denial of a registration would apply to section 3(c)(6) denials.

Section 305(b)(2) would amend section 6(a) of the Act by striking out section 6(a)(2). The paragraph to be struck, which requires registrants to submit, to the Administrator, additional factual information regarding unreasonable adverse effects of a pesticide, would be relocated in new subsection (g) of section 6 (to be added by section 305(a)).

Sections 305(b)(2) and 305(b)(3) would strike out language in sections 6(a)(1) and 6(e)(1) of the Act that provide authority for the Administrator to allow the continued use, distribution, or sale of existing stocks of a pesticide whose registration is cancelled. These provisions would be combined in new subsection (g) of section 6 (to be added by section 305(a)).

Section 306—Suspension and cancellation of registration based on false or invalid data

Section 306 would amend section 6 of the Act by adding a new subsection (h) to require the Administrator to immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if, prior to the effective date of the bill, the Administrator has previously determined in the Industrial Biotest validation process that data submitted by a registrant in support of the registration were invalid and (1) have not been replaced or (2) are in the process of being replaced on the effective date of the bill, but have not been submitted by April 1, 1988; and (3) are material to the registration. The term "Industrial Biotest validation process" refers to a United States-Canada cooperative effort, begun in the late 1970s, to review studies by Industrial Biotech Laboratories, Inc., to determine their value.

New subsection (h) further would specify that, if after the effective date of the bill, the Administrator determines that invalid data are submitted or cited by a registrant in support of a registration, the Administrator could (1) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports, or (2) issue a notice of intent to cancel the registration if the Administrator determines that it would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

Also under new subsection (h), if a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator must immediately issue notices of intent to suspend and cancel the registration.

New subsection (h) would establish procedures for hearings on the cancellation or suspension of a registration based on false or invalid data. Any suspension or cancellation under subsection (h) would become final and effective 30 days after receipt by the registrant of a notice issued thereunder unless, during the 30-day period, a request for a hearing is made by a person adversely affected. The hearing would be conducted in accordance with section 6(c) suspension or 6(d) cancellation hearing procedures, as appropriate.

The only matters for resolution at a hearing with regard to data involving the Industrial Biotest validation process would be whether (1) in response to a notice issued by the Administrator under section 3(c)(2)(B) (calling in additional data to support the registration), data previously determined to be invalid have not been replaced as of the effective date of the bill or were in the process of being replaced on the effective date but were submitted to the Administrator by April 1, 1988, and (2) the data are material to the registration. The only matters for resolution at a hearing regarding data submitted in support of registration and determined to be invalid after the effective date of the bill would be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment. The only matters for resolution at a hearing regarding a determination that a registrant willfully submitted material data known to be false in support of a registration would be whether the registrant willfully submitted material data known to be false.

A decision made after completion of any of the above types of hearings will be final. Any such hearing must be held and a determination made under subsection (h) within 75 days after receipt of a request for the hearing.

TITLE IV—RECORDS AND INSPECTIONS

Section 401—Records

Section 401(a) would amend section 8 of the Act to amend subsection (a) and delete subsection (b). Existing subsection (b) would be reincorporated into section 9 of the Act by section 402 of the bill.

Section 8, as rewritten, would retain the substance of current subsection (a) and add related new provisions. Under new subsection (a) of section 8, the Administrator would be authorized to require, by regulation, any pesticide producer, exporter, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility (a new term defined under section 401(b) of the bill), or commercial applicator, or any person who distributes or sells any pesticide, to (1) prepare, and maintain for reasonable periods of time, records that the Administrator finds necessary for the effective implementation or enforcement of the Act; (2) furnish to the Administrator reports stating the location where the records are maintained; and (3) furnish copies of the records to the Administrator on written request. Except as provided in new subsections (c), (d), and (e) of section 8 (to be added by section 601(c) of the bill) relating to applicator certification and training, the Administrator could not require any person who distributes or sells at retail a non-restricted use pesticide to prepare, maintain, or furnish any record for that pesticide under new subsection (a).

Under new subsection (b), the Administrator could not require any person to maintain records of: (1) financial data, sales data, or pricing data; (2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to the exposure; or (3) research or test data (other than data relating to registered pesticides, data relating to any pesticide for which an application for registration or for an experimental use permit has been filed, or data relating to testing at a pesticide testing facility).

Section 401(b) would amend section 2 of the Act to add a new subsection (hh) defining the term "pesticide testing facility". Under the new definition, the term means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing it). The term would not include any person solely on account of the person's participation as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under the Act.

Section 401(c) would make amendments to section 26(c) of the Act to conform with the amendments made by sections 401 and 402 of the bill.

Section 402—Inspections

Section 402(a) would amend subsection (a) of section 9 of the Act, which currently provides general authority for the Administrator, in enforcing the Act, to enter premises and inspect and obtain samples of pesticides. New subsection (a), as amended by section 402(a), would retain the substance of the first sentence of current subsection (a), add provisions (currently in section 8) relating to copying of records, and add related new provisions. The last five sentences of current subsection (a) would be deleted, but the maters they cover would be included in new subsection (d) of section 9, to be added by section 402(c) of the bill. Under new subsection (a), officers or employees of the United States or of any State, duly designated by the Administrator will be authorized, at reasonable times, to (1) enter any place where any pesticide, active ingredient, or device is distributed or sold to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at the pace or of any packaging or labeling of the pesticide, active ingredient, or device; (2) enter any place where there are located any records required by the Act, including any place reported under new subsection (a) of section 8, to be added by section 401(a) of the bill, as a location where records are maintained, to inspect and obtain copies of the records; (3) enter any pesticide testing facility (a new term defined under section 401(b) of the bill) to inspect the facility and the testing being conducted at the facility and inspect and obtain copies of any records required by the Act to be maintained by the pesticide testing facility; and (4) enter any place where the officer or employee has reason to believe that the Act has been or is being violated by any person other than a private applicator, to inspect the place and obtain evidence of the violation.

It is the intent of the Committee that with respect to pesticide testing facilities, the duly designated officer or employee should be technically qualified to inspect such facility and the testing being conducted therein. The Committee believes that it should be clear whether the State agency or EPA has primacy for enforcement action as provided for in section 26 of the Act.

Section 402(b) would amend subsection (b) of section 9 of the Act, which deals with entry, inspection, and seizure warrants. Under new subsection (b), authority would be provided for officers or employees of the United States or of any State, duly designated by the Administrator, to obtain and to execute warrants authorizing (1) entry, inspection, and obtaining of evidence for the purposes of section 9, as revised by the bill; (2) inspection and copying of all records required under the Act; and (3) seizure of any pesticide or device that is in violation of the Act. New subsection (b) retains the substance of current subsection (b), as implemented by the Environmental Protection Agency.

Section 402(c) would amend section 9 of the Act by adding a new subsection (d) relating to the procedures to be followed before entry or inspection of premises is made. The provisions of new subsection (d) are similar to those of the last three sentences of current section 8(b) (to be deleted under section 401(a)) and the last five sentences of current section 9(a) (to be delted under section 402(a)).

Specifically, new subsection (d) provides that, before making any entry or inspection of any premises not open to the general public under section 9, as amended, the person conducting the inspection must present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the inspection and whether a violation of the Act is suspected. Each entry or inspection must be commenced and completed with reasonable promptness. If the person conducting the entry or inspection obtains any samples of pesticides or devices before leaving the premises, the person must leave with the person in charge a receipt describing the samples and, if requested and practicable, a portion of each sample equal in volume or weight to the portion retained. If an analysis of the sample is made a copy of the results of the analysis must be furnished on request to the person in charge of the premises.

Section 402(c) also would add a new subsection (e) to section 9, requiring the Administrator to coordinate actions taken under section 9 with actions taken under other Federal laws to avoid duplicate inspections.

Section 402(c) also would add a new subsection (f) to section 9 to authorize an officer or employee of the United States or of any State, duly designated by the Attorney General, to obtain and execute a warrant in accordance with Rule 41 of the Federal Rules of Criminal Procedure if a court or magistrate determines there is probable cause to believe a criminal violation of the Act has occurred or is occurring on the property to be entered or searched; or evidence of a criminal violation of the Act will be found on the property.

TITLE V—EXPORT OF PESTICIDES

Section 501—Definition of misbranded

Section 501 would amend section 2(q)(1) of the Act, which defines the term "misbranded" by listing a number of situations in which a pesticide would be considered misbranded. The amendment made by section 501 would add a new provision to the list in section 2(q) to provide that a pesticide intended for export and substantially similar in composition and use pattern to a registered pesticide will be misbranded if the label is not written in an appropriate language, as required by new subsection (a)(4)(A) of section 17 of the Act (to be added by section 503(a) of the bill), or does not contain the same health, safety, and hazard precautions as the pesticide registered under the Act unless the precautions on the label are in conflict with laws of the importing country.

Section 502—Definition of importing country

Section 502 would amend section 2 of the Act to add a new subsection (ii) to define the term "importing country". Under the new definition, the term means the first country to which a pesticide, device, or active ingredient subject to the notification requirements of new subsection (a) of section 17 of the Act (to be added by section 503(a) of the bill) is exported from the United States.

Section 503—Pesticides and devices intended for export

Section 503(a) would amend subsection (a) of section 17 of the Act, which imposes requirements applicable to exported pesticides. Paragraph (1) of new subsection (a) provides that, notwithstanding any other provision of the Act, no pesticide, device, or active ingredient used in producing a pesticide intended solely for export to any foreign country will be considered in violation of the Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of the pesticides, devices, and active ingredients used in producing pesticides will be subject to provisions of the Act that—

(1) define label and labeling;

(2) provide that a pesticide is misbranded under certain conditions;

(3) require the registration of establishments;

(4) provide for records and recordkeeping; and

(5) in new subsection (a), regulate pesticides and devices intended for export.

This provision is the same as existing law, except that exporting producers would also be made subject to the misbranding provisions of section 2(q)(1)(I) of the Act, to be added by section 501 of the bill.

Paragraph (2) of new subsection (a) would restrict the export of a pesticide, device, or active ingredient (1) for which a restricted use classification has become effective; (2) for which a cancellation or suspension has become effective; (3) the registration of which has been voluntarily withdrawn by the registrant, if the withdrawal is associated with concern over potential adverse public health or environmental effects; or (4) that is not registered for any use. Export of the pesticide, device, or active ingredient described above would be allowed only if, at least 30 days before the first shipment each year, the Administrator has provided notice in accordance with paragraph (3) to the appropriate government regulatory office in the importing country; and prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that the pesticide is not registered for use in the United States and cannot be sold in the United States under the Act. A copy of the statement signed by the foreign purchaser would be transmitted to an appropriate official of the government of the importing country. Such documents would be made available to the public on request.

Paragraph (3) of new subsection (a) provides that the notification required by paragraph (2) must be made in an appropriate language and contain the—

(1) name of the pesticide and the common and chemical names of the active ingredients;

(2) name and address of the person exporting the pesticide, device, or active ingredient;

(3) name and address of the person importing the pesticide, device, or active ingredient;

(4) name and address of the appropriate government regulatory office in the importing country;

(5) reasons why the registration was cancelled, suspended, voluntarily withdrawn, or classified for restricted use (and the list of restrictions) or a statement that the pesticide ingredient is not registered in the United States; and

(6) name and address of the office of the Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

Paragraph (4) of new subsection (a) would require that the label of pesticides intended for export from the United States be written in an appropriate language. Labels of pesticides intended for export could not refer to compliance with the laws of the United States, except for a statement (required under section 2(q)(1)(H) of the Act) that the pesticide is "Not Registered for Use in the United States", unless the label also contains or is accompanied by a description of the relevant requirements of the law.

Paragraph (5) of new subsection (a) authorizes the Administrator by regulation to require any person subject to subsection (a) to prepare, maintain, and submit such records as may be necessary to carry out subsection (a).

Section 503(b) provides that the export restrictions and notification provisions of paragraphs (2) and (3) of new subsection (a) will become effective 90 days after the date of enactment of the bill. Section 503(b) also provides that, not later than 30 days after the date of enactment of the bill, the Administrator must publish in the Federal Register a list of the names, addresses, and the international telecommunications codes of appropriate regulatory offices required to receive notices under paragraph (2). Not later than 180 days after the date of enactment, and annually thereafter, the Administrator must revise the list of regulatory offices of importing countries designated to receive notices.

Section 503(b) also would require that, not later than 90 days after the date of enactment of the bill, the Administrator must publish in the Federal Register preliminary guidelines regarding the form of notification under new subsection (a), translation of the notification and labels required, preparation and retention of records by exporters, and procedures for public access to documents submitted by exporters.

Section 504—Cancellation notices furnished to foreign governments

Section 504 would amend subsection (b) of section 17 of the Act retaining the substance of current law and adding related provisions. New subsection (b) would require the Administrator promptly to transmit through the Secretary of State a notice to the appropriate governmental regulatory offices of other countries and to appropriate international agencies whenever (1) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective, or (2) a pesticide is classified for restricted use. Such notice also must be retransmitted annually to the office or agency described above.

The contents of the notice must include (1) the reasons for the regulatory action taken; (2) for cancelled or suspended registrations, information concerning other registered pesticides that could be used in lieu of the pesticide; and (3) the name and address of the office of the Environmental Protection Agency that on request can provide additional information on the pesticide.

TITLE VI—CERTIFICATION AND TRANING

Section 601—Certification, training, and recordkeeping amendments

Section 601(a) would revise section 2(e) of the Act, which contains definitions relating to persons who apply pesticides. As revised, section 2(e) provides that—

(1) the term "commercial applicator" is to mean a person (whether or not the person is a private applicator with respect to some uses) who (a) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use; (b) uses or supervises the use of any pesticide for hire as the principal part of the person's business or work; or (c) (as an employee of a person that uses or supervises the use of any pesticide for hire as the *principal part* of the person's business or work) uses or supervises the use of any pesticide. The term does not include a person who uses or supervises the use of a pesticide as a private applicator. It is the intent of the Committee that, in defining the term "principal part" in implementing this definition, the Administrator exclude from the commercial applicator category persons engaging in the occasional use of pesticides, but include those persons who use pesticides with such regularity and frequency as to pose a potential threat to the public health, the environment, or themselves without the training required of commercial applicators;

(2) the term "private applicator" is to mean a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the person or the person's employer or on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) the term "certified applicator" is to mean a commercial or private applicator who is certified under section 4 of the Act (which will be substantially amended under section 601(b)); and

(4) with respect to the term "under the direct supervision of a certified applicator", unless otherwise prescribed by its labeling, a pesticide is to be considered to be applied under the direct supervision of a certified applicator if it is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though the certified applicator is not physically present at the time and place the pesticide is used.

The new definitions of "private applicator" and "under the direct supervision of a certified applicator" are substantially the same as existing law. The new definition of "certified applicator" revises the current definition in the first sentence of section 2(e)(1) to reflect the other changes in the Act made by title VI. The second sentence of section 2(e)(1) is deleted, but substantially retained in the definition of "to distribute or sell' in new subsection (kk) of section 2, to be added by section 802(a) of the bill. The new definition of "commercial applicator" would expand the definition in current law by adding the provisions described in clauses (b) and (c) of item (1) above.

Section 601(a) also would amend section 2 of the Act to add a new subsection (jj) to define the term "pesticide dealer". Under new subsection (jj), the term means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or is designated by the Administrator, by regulation under new subsection (d)(2) of section 8 of the Act (to be added by section 601(c)), as a pesticide that may cause significant adverse effects on health or the environment. The term does not include a person who only distributes or sells pesticides that are classified for general use and not so designated by the Administrator, by regulation, as pesticides that may cause significant adverse effects on health or the environment.

Section 601(b) would amend section 4 of the Act (which deals with the use of restricted use pesticides and the certification of applicators) by adding new subsections (d) through (l).

New subsection (d) provides rules with respect to the training and certification of commercial applicators.

Under paragraph (1) of new subsection (d), it would be a violation of the Act for any person to use any pesticide as a commercial applicator unless the person is a certified commercial applicator, or a registered commercial applicator under the direct supervision of a certified applicator who is a certified commercial applicator.

Under paragraph (2) of new subsection (d), to be considered to be a *certified* commercial applicator, a person must at a minimum—

> (1) have met the standards prescribed under subsection (a) of section 4 of the Act and have received training prescribed by the State agency responsible under section 4 for administering certification activities in the State involved (including training using material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g) of section 4 (to be added by section 601(b) and conducted by a trainer who has met requirements under new subsection (h) of section 4 (to be added by section 601(b))) that satisfies the minimum standards for training programs under new subsection (h);
>
> (2) have field, institutional, or industrial experience in pesticide use and application;
>
> (3) have passed an examination prescribed by the State agency; and
>
> (4) posses a valid commercial applicator certification issued by the State agency.

Under paragraph (3) of new subsection (d), to operate as a *registered* commercial applicator, a person at a minimum must have received training prescribed by the State agency (including training using the material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g)) conducted by a trainer who has met requirements under new subsection (h), and possess a valid registration by providing to the State agency a report, signed and dated by the trainer and the person who received the training, stating that the prescribed minimum training has been provided and received.

New subsection (e) provides rules with respect to the certification and training of private applicators.

Under paragraph (1) of new subsection (e), a restricted use pesticide would be considered to have been applied by or under the direct supervision of a certified private applicator only if it is applied by a person who is either a certified private applicator, or a supervised private applicator who uses a pesticide under the direct supervision of a certified private applicator.

Under paragraph (2) of new subsection (e), to be considered to be a *certified* private applicator a person at a minimum must have (1) met the standards prescribed under subsection (a) of section 4 and have received training prescribed by the State agency (including training using the material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g)), conducted by a trainer who has met requirements under new subsection (h), that satisifes the minimum standards for training under new subsection (h), and (2) possess a valid private applicator certifiation issued by the State agency.

Under paragraph (3) of new subsection (e), to be considered to be a *supervised* private applicator a person at a minimum must have received basic instruction prescribed by the State agency or based on material prescribed by the State agency or based on material prescribed by the State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling. The training must be given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the minimum standards for trainers under new subsection (h). The State agency could require the employer of a supervised private applicator to confirm that the basic instruction described above has been received.

New subsection (f) deals with recertification and reregistration. New subsection (f) would require each certified applicator and each registered commercial applicator within a State to undergo refresher training and be recertified or reregistered within a period established by the State agency but not to exceed 5 years. The refresher training must be prescribed by the State agency and include training in the materials established by the Administrator in cooperation with the Secretary of Agriculture under new subsection (g) and in the relevant requirements of the other subsections of section 4 and section 3(d) (classification of pesticides), section 12 (unlawful acts), and section 14 (penalties) of the Act. To be *recertified,* an applicator at the minimum must meet the requirements of paragraph (2) of new subsection (d) (other than the examination requirement) or the requirements of paragraph (2) of new subsection (e), as applicable. To be *reregistered,* a commercial applicator must meet the requirements of paragraph (3) of subsection (d).

New subsection (g) deals with applicator training. New subsection (g) would require the Administrator in consultation with the

Secretary of Agriculture to develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling. Within 12 months after the effective date of the bill the Administrator, in consultation with the Secretary of Agriculture, must revise and make current the materials and thereafter update as needed.

New subsection (h) deals with minimum standards for trainers and training materials.

Paragraph (1) of new subsection (h) would require the Administrator to establish, within one year after the effective date of the bill, minimum standards of competency, and experience or expertise, for trainers referred to in new subsection (d), and minimum standards for the training programs referred to in subsection (d). The training programs under subsection (d) must comply with the minimum standards established by the Administrator within two years after the effective date of the standards. If after the two-year period, a State's training program fails to meet the minimum standards, or if a State fails to prescribe the program, the Administrator must notify the State of the failure. After receipt of the notice, a State will have 90 days to bring its training program into compliance with the standards, after which time, if the program does not meet the standards, the Administrator must prescribe the training programs referred to in subsection (D).

Under paragraph (2) of new subsection (h), the Administrator must establish (within two years after the effective date of the bill) minimum standards of competency, and experience or expertise, for trainers referred to in new subsection (e), and minimum standards for the training programs referred to in subsection (e). Training programs prescribed by any State under subsection (e) must comply with the minimum standards not later than two years after the effective date of the standards. If on the expiration of such two-year peirod a State's training program fails to meet the minimum standards, or if a State fails to prescribe the program, the Administrator must notify the State of the failure. After receipt of the notice, a State would have 90 days to bring its training program into compliance with the standards. If after the 90-day period the State's training program does not meet the standards, the Administrator must prescribe the training programs referred to in subsection (e) for use in the State. In general, it is the intent of the Committee that these amendments should be construed in a manner that encourages the States to employ reciprocity for the satisfaction of training requirements in situations where applicators are applying pesticides in more than one State. Reciprocity among the States should be considered an effective means of achieving a consistently high level of competency while encouraging the free flow of commerce across State lines.

New subsection (i) deals with privately administered training programs. Under new subsection (i), a State agency could approve any privately administered training program that it determines meets the requirements established under section 4, or requirements established by the State agency, whichever are more stringent.

New subsection (j) deals with enforcement officer training. New subsection (j) provides that Federal and State field personnel responsible for on-site observations and inspections of pesticide use must have training that, at a minimum, includes training covering materials specified in new subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

New subsection (k) provides that in establishing standards under section 4 applicable to applicators, the Administrator must establish separate standards for commerical applicators and private applicators.

New subsection (1) provides that, for the purposes of section 4, the term "State agency" means the agency of a State that is designated in the State certification plan under subsection (a) of section 4 as the agency responsible for administering the plan throughout the State, if the State has primary enforcement responsibility for pesticide use violations as provided for under section 26 of the Act. In the case of a State that does not have primary enforcement responsibility or that does not have an agency designated in the State plan, a reference to a State agency would be considered a reference to the Administrator.

The amendments to section 4 made by section 601(b) would be phased in as follows:

Subsection (d): Except as provided below, the provisions of new subsection (d) would take effect in a State on the expiration of the two-year period prescribed by new subsection (h) (within which training programs of the State are to be in compliance with minimum standards prescribed by the Administrator—which the Administrator will have one year after the effective date of the bill to establish). If an applicator in a State is certified as a commercial applicator under subsection (a) of section 4 before the effective date described above and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (d), the applicator must be recertified within two years after the date the training programs of the State comply with the minimum standards of the Administrator, or within an earlier time as the State may prescribe. The requirements of subsection (d), for registered commercial applicators would take effect one year after the expiration of the compliance period prescribed by subsection (h).

Subsection (e): Except as provided below, the provisions of new subsection (e) would take effect in a State on the expiration of the compliance period prescribed by subsection (h). If an applicator in a State is certified as a private applicator under subsection (a) before the effective date described above and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (e), the applicator must be recertified within two years after the date the training programs of the State comply with the minimum standards of the Administrator, or within an earlier time as the State could prescribe. The requirements of subsection (e) for supervised private applicators would take effect one year after the expiration of the compliance period prescribed by subsection (h).

Subsection (j): The requirements of new subsection (j) regarding enforcement officer training would take effect one year after the Administrator issues the training materials specified in new subsection (g).

Section 601(c) would amend section 8 of the Act (records) to add new subsections (c) through (f).

New subsection (c) provides rules regarding applicator records. It provides that the Administrator must require each commercial applicator to maintain records of pesticide applications, including the identity and amount of the pesticides applied and the date and location of the applications, for a period of two years after each application. No regulations prescribed by the Administrator under the Act could require any private applicator to maintain any records or file any reports or other documents.

New subsection (d) deals with pesticide dealer records. It provides that the Administrator, by regulation, must require each pesticide dealer to maintain a record of each sale or distribution of (1) a pesticide classified for restricted use and (2) any other pesticide designated by the Administrator by regulation because it may cause significant adverse effects on health or the environment. The records must include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer must maintain the records for three years after the date of the distribution or sale.

New subsection (e) deals with access to records and enforcement findings. It provides that any pesticide dealer or commercial applicator must afford, to any employee or former employee of the dealer or applicator, access to records required to be kept under new subsections (c) and (d) that directly relate to the employee's employment duties. Each pesticide dealer or commercial applicator must afford to any customer of the dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by the applicator at the request of the customer or under a contract with a customer.

Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, must make available reports of the findings of the investigation or action to the complainant. On the request of a complainant, the agency must provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action. The records for which access is provided must be accessible within 30 days after the public health or in a medical emergency, the records must be provided as soon as possible, but no later than 24 hours after the request is made.

A copy of any record required to be maintained under subsection (c) or (d) must be submitted, on request, to a State agency with primary enforcement responsibility under section 26 of the Act.

Under new subsection (f), an employer who uses or supervises the use of a pesticide must know or have access to the brand name and common or chemical name of each ingredient listed on the labeling of the pesticide, and know or have access to the safety, first aid, and antidote information listed on the labeling of the pesticide, and must be responsible for promptly making the information available, on request, to any employee exposed to a pesticide and to treating medical personnel. It is the intent of the Committee that such information also would be made available to former employees for a reasonable period of time.

Section 601(c) would repeal section 11 of the Act (standards applicable to pesticide applicators) to conform with the amendments made to section 8 of the Act, as described above.

Section 601(d) would amend section 12 of the Act (unlawful acts) to make it a violation of the Act to obtain and use records acquired under new subsection (e) of section 8 (to be added by section 601(c) of the bill) in furtherance of a commercial purpose.

TITLE VII—DATA COMPENSATION

Section 701—Defensive data

Section 701 would amend clauses (i) and (ii) of section 3(c)(2)(B) of the Act relating to the joint development of additional data to support existing registrations of pesticides by two or more registrants. As rewritten, clause (ii) will have four subclauses.

Clause (i) currently provides that if the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator must notify the registrant of each pesticide to which the determination relates and provide a list of the registrants to any person. Clause (i) would be amended to apply also to existing registrations of groups of pesticides.

Under current law, each registrant of a pesticide for which additional data are needed to support the registration must provide evidence, within 90 days after receipt of notification by the Administrator that the additional data are needed, and that it is taking appropriate steps to secure the data. This provision is expanded to include taking appropriate steps to submit the data and will be included in new clause (ii) as subclause (I).

The second and third sentences of clause (ii) currently provide that two or more registrants may agree to develop jointly, or share in the cost of developing, such data if they agree and advise the Administrator within 90 days after notification; and that a registrant who agrees to share in the cost of data is entitled to examine and rely on the data in support of the registration. This provision is amended and included as new subclause (II) to clause (ii). Subclause (II) provides that two or more registrants may agree to develop jointly, or to share in the cost of developing such data. Any registrant who enters into such an agreement, or who offers to agree to share in the cost of development of such data, would be entitled to examine the data and rely on the data to maintain or obtain registrations under the Act or under State law. An offer to enter into such an agreement may be accepted at any time and may not be withdrawn without the consent of the person to whom the offer was made.

Section 701 also would amend the provision of clause (iii) of section e(c)(2)(B) concerning binding arbitration proceedings to establish the terms of the data development arrangement or agreement. As amended, clause (iii) provides that if at the end of 60 days after two or more registrants have entered into an agreement under clause (ii) the registrants have not further agreed on the terms of the data development or cost-sharing agreement or on a procedure for reaching such an agreement, any of the registrants may initiate binding arbitration proceedings to fix such terms by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by the Service.

Section 702—Data compensation and arbitration

Section 702(a) would amend section 3(c)(1)(D) relating to the compensation of original data submitters.

Under current law clause (ii) of section 3(c)(1)(D) provides that, subject to the exclusive use provisions of clause (i), with respect to data submitted after December 31, 1969, to support applications under the Act, existing registrations, and registration, the Administrator can consider the data (without the permission of the original data submitter) in support of an application by any other person (the "applicant") within the 15-year period after the data were submitted only if the applicant makes an offer to compensate the original data submitter. The terms and amount of compensation are to be fixed by agreement between the original data submitter and the applicant or, failing agreement, *binding* arbitration as provided for in clause (ii). Either party can initiate the binding arbitration proceedings if they cannot reach agreement on the terms and amount of compensation within 90 days after the applicant's offer to compensate is delivered to the data submitter. The parties to the arbitration must share equally in the fees and expenses of the arbitrator.

Section 702(a) would redesignate clause (iii) as clause (iv) and provide for a new clause (iii). New clause (iii) would provide that in the case of a pesticide for which the patent has expired, the terms and amount of compensation, for data that was submitted for that pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites that data may be fixed *before* the submission of the application by arbitration under clause (ii) initiated by the applicant. The arbitration would be binding on the original data submitter and also would be binding on the applicant after the date the application is submitted. The findings and determination of the arbitrator would be subject to judicial review in the United States Court of Appeals on the filing of an action by a party to the arbitration up to the date the applicant submits the application. The findings and determination of the arbitrator with regard to issues of fact would be sustained if they are supported by substantial evidence when considered on the record of the arbitration as a whole.

Each party to the first arbitration under clause (iii) to determine the terms and amount of compensation for the use of particular data would share equally in the payment of the fees and expenses of the arbitrators and would each pay its own attorney's fees. In all subsequent arbitrations under clause (iii) to determine the terms and amount of compensation for the use of the data, the party to the subsequent arbitration who seeks to cite the data of the original data submitter must pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter.

Clause (iii) also provides that clause (ii) would apply to arbitrations under clause (iii), except as otherwise provided in clause (iii).

Section 703—Restoration of patent term for certain agricultural and chemical products

Section 703 adds a new section 158 to title 35 of the United States Code.

Paragraph (1) of new section 158(a) provides that the term of a patent that claims a product subject to a regulatory review period or a method for using or manufacturing such a product will be extended in accordance with new section 158 from the original expiration date of the patent if certain prerequisites are met. These prerequisites include (A) in accordance with other provisions of the bill, the Commissioner of Patents and Trademarks must be notified by the product sponsor of facts suppportive of a request for patent term restoration, (B) the regulatory review period for the product in question must have occurred prior to commercial marketing or use of the product, (C) the patent term was never previously extended, and (D) the patent term had not expired prior to the abovementioned notification to the Commissioner.

Paragraph (2) of new section 158(a) limits the rights derived from any claim of an extended patent to (A) the "scope of such claim that relates to the product subject to regulatory review" and, (B) in the case of a patent that claims a method of manufacturing a product, to the method of manufacturing as used to make the approved product.

Subparagraph (A) of new section 158(a)(3) provides that the term of a patent would be extended by the time equal to the regulatory review period that occurred after the patent was granted. This extension, however, is subject to several additional limitations enumerated in subparagraph (B) of new section 158(a)(3).

Subparagraph (B)(i) of new section 158(a)(3) provides that any regulatory review period which is to be applied for purposes of extending the patent shall be reduced by certain periods during which applications for premarket approval were made under relevant statutes, but not accepted by the relevant agencies because the applications did not contain sufficient data or information. However, if during the period the product sponsor conducts a major health or environmental effects test, the period during which such test is conducted would not be excluded.

Subparagraph (B)(ii) of new section 158(a)(3) provides that any regulatory review period to be applied for purposes of patent term extension would further be reduced by any period during which the applicant for the patent term extension did not act with due diligence, as determined under new section 158(b)(2).

Subparagraph (B)(iii) of new section 158(a)(3) provides that no patent term may be extended for more than 5 years, and that no term of any extended patent may exceed 25 years from the filing date of its earliest related U.S. patent application. In cases in which the regulatory review period had not ended at the date of enactment, the period of extension for the patent would be measured from the enactment date but would not exceed 3 years. If, however, the regulatory review period had ended before enactment of new section 158, no patent term extension would be permitted.

Subparagraph (C) of new section 158(a)(3) provides that not more than one patent may be extended for the same regulatory review of a specific product.

Subparagraph (D) of new section 158(a)(3) provides that for purpose of the extension of a patent term relating to a pesticide, each formulation of the pesticide containing the identical active ingredient would be considered the same pesticide, and no pesticide may be the subject of more than one patent extension.

New section 158(b)(1) sets forth the procedures to be followed in seeking and obtaining an extension of a patent term, and specifies the information which must be submitted to the Commissioner of Patents and Trademarks. Subsection (b)(1) requires that within 60 days after termination of a regulatory review period, the product sponsor seeking extension of the patent term must notify the Commissioner that the regulatory review period had ended. If the product sponsor is not the owner of record of the patent, the notification must include the written consent of the owner of record of the patent. Notification by the product sponsor to the Commissioner must (A) identify the Federal statute under which the regulatory review occurred; (B) state the dates on which that regulatory review began and ended; (C) identify the product for which regulatory review was required; (D) state that the requirements of the statute under which regulatory review occurred were satisfied so that commercial marketing or use of the product is not prohibited under the Federal statute which provided for the regulatory review in question; (E) identify the patent and any claim thereof to which the extension is applicable; identify the filing date of the earlier United States Patent application to which reference is made in subsection (a)(3)(B)(iii) of new section 158; state that the term of the patent has never been extended, and that no other patent had been extended on the basis of the same regulatory review period; and (F) include any other information which the Commissioner may require.

New section 158(b)(2)(A) provides that within 60 days after submittal of the extension notification, the Commissioner must notify the Administrator of the Environmental Protection Agency if the patent claims a pesticide subject to the Act, a chemical substance or mixture subject to the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), or a method of using or manufacturing such a pesticide, substance, or mixture, of the extension notification and also must submit a copy of the extension notification to the Administrator.

Not later than 30 days after receipt of the copy of the extension notification from the Commissioner, the Administrator must review the dates enumerated in the notification and determine the applicable regulatory review period for the particular product in question. The Administrator must notify the Commissioner of the determination and publish notice of the determination in the Federal Register.

Subparagraphs (B) and (C) of new section 158(b)(2) provide for the determination of the product sponsor's due diligence during the regulatory review period on the basis of a petition submitted to the Administrator.

Subparagraph (D) of new section 158(b)(2) provides that failure of a product sponsor to act with due diligence during a regulatory review period would not be a defense in any action involving the infringement of the patent in question.

Subparagraph (E) of new section 158(b)(2) defines the term "due diligence" for purposes of paragraph (2) of new section 158(b) to mean that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

Subparagraph (F) of new section 158(b)(2) authorizes the Administrator to take into consideration when determining whether the product sponsor exercised due diligence during the regulatory review period the failure of a product sponsor to submit data that the product sponsor knew or reasonably should have known was necessary to support an application or notice described in subsection (c)(4) of new section 158.

Subparagraph (G) of new section 158(b)(2) authorizes the Administrator and the Commissioner to establish fees to cover the costs of carrying out their respective duties and functions under new section 158.

Paragraph (3)(A) of new section 158(b) requires the Commissioner to determine that a patent is eligible for extension in accordance with the requirements of subsections (a) and (b)(1) of new section 158. Such a determination may be based solely on the representations contained in the notification provided by the product sponsor under subsection (b)(1) of new section 158. If the Commissioner determines that a patent is eligible for extension, and upon receipt of a final determination of the applicable regulatory review period, the Commissioner must issue to the patent owner of record a certificate of extension of the patent, stating the length of extension, identifying the product and the statute under which regulatory review occurred, and specifying the claim to which such extension is applicable. The certificate of extension must be recorded in the official file of the patent and would be considered part of the original patent. A notice of the extension is also published in the Official Gazette of the Patent and Trademark Office.

Subparagraph (B) of new section 158(b)(3) provides that if the original term of the patent for which extension is sought would expire before a final decision by the Commissioner to issue a certificate of extension, the Commissioner must extend, until the determination is made, the term of the patent for periods of up to one year if the Commissioner determines that the patent is eligible for extension.

Section 158(b)(4) provides that if information submitted during a regulatory review period by a product sponsor which is considered a trade secret, or confidential commerical or financial information under the law which mandates the regulatory review, the information may only be disclosed under new section 158 in accordance with such law. However, the Administrator may disclose information necessary to publish a notice and hold a hearing under subsection (b)(2) of new section 158.

New section 158(c) defines terms used in new section 158 as follows:

Paragraph (1) of new section 158(c) defines the term "Administrator" to mean the Administrator of the Environmental Protection Agency.

Paragraph (2) of new section 158(c) defines the term "product" to mean any machine, manufacture, or composition of matter for which a patent may be obtained. However, the term "product" is limited to any chemical substance or mixture subject to regulation under the Toxic Substances Control Act or any pesticide subject to regulation under the Act.

Paragraph (3) of new section 158(c) defines the term "major health or environmental effects test" to mean an experiment or study to determine or evaluate health or environmental effects that requires at least six months to conduct, not including any period for analysis or conclusions, and the data from which is submitted to receive permission for commercial marketing or use.

Paragraph (4) of new section 158(c) defines the term "product sponsor" to mean any person who, with the consent of the patent owner, initiates testing or investigation, claims an exemption, or submits an application, petition, protocol, request, or notice.

Paragraph (5) or new section 158(c) defines the term "regulatory review period" as follows.

Subparagraph (A) of new section 158(c)(5) defines the regulatory review period with respect to pesticides regulated under the Act. The term means the sum of (i) the period beginning on the earlier of the date the product sponsor (I) initiates a major health or environmental effects test on such pesticide, or (II) requests, in accordance with regulations issued by the Administrator, the grant of an experimental use permit for the pesticide under section 5 of the Act and ending on the date an application is submitted for registration of such pesticide pursuant to section 3 or such Act; and (ii) the period beginning on the date an application is submitted, in accordance with regulations issued by the Administrator, for registration of such pesticide pursuant to section 3 of the Act and ending on the date such pesticide is first registered, either conditionally or fully, under that section.

Subparagraph (B) in new section 158(c)(5) defines the "regulatory review period" for chemical substances or mixtures subject to regulation under the Toxic Substances Control Act as follows. The term means for chemical substances and mixtures that (i) are subject to a rule requiring testing under section 4(a) of the Toxic Substances Control Act, a period commencing on the date the product sponsor has initiated the testing required in such rule and ending on the expiration of the notice period for such chemical substances or mixture under section 5 of that Act, or if an order or injunction is issued under section 5(e) or 5(f) of that Act, the date on which such order or injunction is dissolved or set aside; or (ii) are not subject to a testing rule under section 4 of that Act, a period commencing on the earlier of the date the product sponsor (I) submits, in accordance with regulations issued by the Administrator, a notice under section 5 of that Act, or (II) initiates a major health or environmental effects test on such chemical substance or mixture, and ending on the expiration of the notice period for such substance under section 5 of that Act or if an order or injuction is issued under section 5(e) or 5(f) of that Act, the date on which such order or such injunction is dissolved or set aside. No regulatory review period would be deemed to have commenced until a patent had been granted for the product that is subject to regulatory review, for the method for using such product, or for the method for producing such product.

Section 703(b), which concerns the infringement of pesticide patents, adds a new subsection (g) to section 271 of title 35 of the United States Code.

New subsection (g)(1) provides that except as provided in paragraph (2) of new subsection (g), during the last 2 years of the term of a patent relating to a pesticide (including a patent that claims the pesticide, a method for using the pesticide, or a method for manufacturing the pesticide) that is or has been registered under the Act, or that is marketed with the permission of the patent holder, it would not be an act of infringement of the patent (A) to make, use, or sell the pesticide solely for testing reasonably related to the development and submission of data to comply with such Act; or (B) to obtain a tolerance, exemption from the need for a tolerance, or food additive regulation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

Paragraph (2) of new subsection (g) provides that if the patent of the pesticide is extended under new section 158, and the extension is for less than 2 years, the period during which such testing may occur without infringement would begin 1 year before the patent expires.

Paragraph (3) of new subsection (g) provides that paragraphs (1) and (2) of new subsection (g) would apply only to the first patent the effect of which was to make an infringement the unlicensed manufacture, use, or sale of the patented product as a pesticede.

Paragraph (4) of new subsection (g) provides that it would be an act of infringement for any person, other than the patent holder or the licensee of the patent, to submit an application for registration under the Act of a pesticide covered by the first patent, as described in paragraph (3) of new subsection (g), before expiration of such patent.

Paragraph (5) of new subsection (g) provides that for purposes of this paragraph, each formulation of a pesticide containing the identical active ingredient would be considered the same pesticide.

Section 703(c) amends the analysis for Chapter 14 of title 35 of the United States Code to include a new heading for section 158.

TITLE VIII—GENERAL

Subtitle A—Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act

Section 801—Authority of States

Section 801(a) redesignates and restates existing section 24(a) of the Act as new section 24(a)(1) and provides that a State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by the Act.

Section 801(a) also amends existing section 24(a) by adding a new paragraph (2).

Subparagraph (A) of new section 24(a)(2) would apply to any house or garden pesticide where (i) the pesticide is a formulated end-use product; (ii) the pesticide has been registered under section 3(c)(5) of the Act or reregistered under section 3A of the Act after the effective date of the bill; (iii) the Administrator has determined that the product as registered or reregistered poses no significant toxicological concern; and (iv) the Administrator has published the determination of no significant toxicological concern in the Federal Register.

Subparagraph (B) of new section 24(a)(2) provides that except as provided in subparagraph (C) of new section 24(a)(2), a State may not prohibit any sale or use permitted under the Act of a pesticide described in subparagraph (A) of new section 24(a)(2) for which an application for State registration has been filed unless and until the State has finally acted on the application pursuant to applicable State law.

Subparagraph (C) of new section 24(a)(2) provides that paragraph (2) of new section 24(a) would not preclude a State from prohibiting the sale or use of a pesticide if the State requires in the State registration process additional toxicity data beyond that required by the Administrator.

Section 801(b)(1) would amend section 24(c) of the Act to require that, when a State provides a registration for additional uses of a Federally registered pesticide to meet special local needs, the registration will expire and be of no further effect (without further action by the Administrator) (A) at the end of the period, if any, provided as the duration of the registration by the State that approved it, or (B) ten days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.

Section 801(b)(2) would further amend section 24(c) to add a new provision requiring the Administrator to establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use. (Note: Under current law, the Administrator has authority, with limits, to disapprove any State special local needs registration during the first 90 days it is in effect).

Section 801(c) would amend section 24 of the Act to add a new subsection (d) relating to differences in usage and risks.

New subsection (d) would provide that in promulgating any regulations or policies pertaining to the sale or use of pesticides within a State, the State must take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the approriate data for evaluating such risk between agricultural and nonagricultural pesticides.

Section 801(d) would amend section 24 of the Act to add a new subsection (e) relating to uniform tolerances for pesticide residues.

Subparagraph (A) of new subsection (e)(1) provides that except as provided in paragraphs (2) and (3) of new subsection (e), no State or political subdivision thereof may, directly or indireclty, establish or enforce any regulatory limit on residues of a pesticide chemical in or on food that is not identical to a permissible residue level established under a Federal law, regulation, or enforcement requirement, if the residues result from use of a pesticide the initial registration or reregistration of which was approved (i) under section 3(c)(5) of the Act on or after April 25, 1985; or (ii) on the basis of data determined by the Administrator to meet the requirements of part 158 of subchapter E of chapter I of title 40, Code of Federal Regulations.

Subparagraph (B)(i) of new subsection (e)(1) provides that except as provided in paragraph (3) of new subsection (e) and notwithstanding any other provision of new subsection (e), no limit imposed by a State on the quantity of a residue of a pesticide chemical that may appear in or on any article of food at a particular level as a result of the application of a pesticide shall apply if, at the time of the application of the pesticide, the sale of such an article of food with such level of residue of such pesticide chemical was lawful under Federal law and the law of such State.

Subparagraph (B)(ii) of new subsection (e)(1) requires the Administrator, in consultation with the Secretary of Agriculture, to consider feasible actions to minimize the duration of distibution of existing stocks of food that contain pesticide residues that comply with Federal and all applicable State laws at the time of pesticide use but that fail to comply with a new State regulatory limit.

Subparagraph (B)(iii) of new subsection (e)(1) requires the Administrator, in consultation with the Secretary of Agriculture, to determine on an annual basis if feasible actions have been taken to minimize the duration of distribution of such stocks of food.

Paragraph (2) of new subsection (e) provides from exemptions the uniform tolerance levels.

Subparagraph (A) of new subsection (e)(2) requires the Administrator, on petition of a State, by regulation promulgated after notice and opportunity for public hearing, to exempt from paragraph (1) of new subsection (e), a State regulatory requirement if the requirement (i) is justified by compelling local conditions; (ii) will not unduly burden interstate commerce; and (iii) will not cause any food to be in violation of Federal law.

Subparagraph (B) of new subsection (e)(2) requires the Administrator, after receiving comment from the Scientific Advisory Panel established under section 25(d) of the Act, to respond to any State petition filed under new subsection (e) within 60 days. If the Administrator fails to respond within 60 days, the State may establish and enforce the regulatory requirement contained in the petition until the Administrator responds to the petition.

Paragraph (3) of new subsection (e) provides that notwithstanding paragraphs (1) and (2) of new subsection (e), a State may, after notice and opportunity for public hearing, establish and enforce within its own jurisdiction a regulatory requirement regarding residues of a pesticide chemical in or on food if the State demonstrates that such requirement to necessary to prevent an imminent hazard of a substantial risk of serious harm to human health during the period required to obtain a response from the Administrator to a petition submitted under paragraph (2) of now subsection (e). A

State must submit a petition under paragraph (2) of new subsection (e) within 10 days after the State promulgates a requirement under subsection (e).

Paragraph (4) of new subsection (e) provides that a person may seek a declaratory judgement under section 2201 of title 28, United States Code, with respect to any requirement established by a State under new subsection (e) on the ground that the requirement does not meet the standards established in new subsection (e). The State would bear the burden of proof in any such action.

Paragraph (5) of new subsection (e) provides that subsection (e) would cease to be effective after September 30, 1991.

Section 802—Definitions

Section 802(a) would amend section 2(ee) of the Act to provide that the term defined therein—"to use any registered pesticide in a manner inconsistent with its labeling"—does not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling (unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency); or (2) employing any method of application not prohibited by the labeling (unless the labeling specifically states that the product may be applied only by the methods specified on the labeling). The words in parentheses are those that would be added to current law by the amendment.

Section 802(a) also would amend section 2 of the Act by adding a new subsection (kk) to define the term "to distribute or sell". Under the new definition, the term means to distribute, sell, offer for sale, hold for distribution hold for sals, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticide products or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

Section 802(b) would make conforming amendments to sections 3(a) and 12(a) of the Act, which currently use essentially the same language as that of new subsection (kk) of section 2, to be added by section 802(b). The amendments would substitute for such language the term defined in subsection (kk)—"distribute or sell".

Section 802(b) would further amend section 12(a) (unlawful acts) to add to the current prohibition under paragraph (2)(F) of section 12(a)—against the use of a restricted use pesticide for purposes not in accord with the Act and its regulations—a prohibition against the distribution or sale (as that term would be defined under new subsection (kk) of section 2) for such purposes.

Section 803—Information requested

Section 803 would amend section 7 of the Act to add a new subsection (f) to require the Administrator, consistent with section 3507(a)(1) of title 44 of the United States Code (public information collection activities), to catalogue and retrieve data in a manner to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data.

Section 804—Cooperative agreements

Section 804 would amend and make technical modifications to subsection (a) of section 23 of the Act. As rewritten, subsection (a) would authorize the Administrator to enter into cooperative agreements and grants with States and Indian tribes to—

> (1) delegate to any State or Indian tribe the authority to cooperate in the enforcement of the Act through the use of its personnel or facilities, train personnel of the State or Indian tribe to cooperate in the enforcement of the Act, and assist States and Indian tribes in implementing cooperative enforcement programs through grants;
>
> (2) provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as agreed under the cooperative agreements, of conducting training programs for the certification of applicators. Funds would be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator; and
>
> (3) provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under the cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State certification plan approved under section 4(a) of the Act. Funds would be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

There would be authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under the subsection.

Section 805—Scientific advisory panel

Section 805 would amend section 25(d) of the Act to expand the FIFRA scientific advisory panel from 7 members to 9 members, and make the panel permanent.

Section 806—Authority for EPA action

Section 806 would amend the second sentence in subsection (a) of section 27 of the Act.

While section 26 of the Act provides for the States to have primary enforcement responsibility with respect to pesticide use violations, section 27 of the Act contains provisions for Federal action on violations when a State fails to ensure enforcement of pesticide use rules.

The second sentence in subsection (a) of section 27 currently provides that the Administrator can act on a pesticide use complaint or information if the State does not commence appropriate enforcement action on the case within 30 days after receiving the complaint or information. As amended, the second sentence would provide authority for the Administrator to act on a complaint or information if a State does not promptly initiate appropriate investigative action after receiving a referral from the Administrator or does not initiate appropriate enforcement action within 90 days after receipt of the referral.

Section 807—Expiration of State primary enforcement responsibility

Section 807 would amend section 26 of the Act by adding a new subsection (d) to provide that the primary enforcement responsibility of a State under the Act with respect to pesticide use violations will expire on January 1, 1990, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in section 14 of the Act.

Section 808—Unlawful acts

Section 808(a) would amend subsection (a) of section 12 of the Act, which describes the acts that are prohibited under the Act. Paragraph (1)(A) of subsection (a) (which currently provides that it is unlawful to distribute or sell pesticides that are not registered except as provided in section 6(a)(1) of the Act (disposal of existing stocks)) would be technically rewritten to provide that it will be unlawful to distribute or sell any pesticide that is not registered under section 3 of the Act or whose registration has been cancelled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under the Act.

Similarly, section 808(a) would technically revise paragraph (2)(B) of subsection (a) to conform to the changes to be made in sections 8 and 9 of the Act by title IV of the bill. Under paragraph (2)(B), as rewritten, it would be unlawful for any person to refuse to—

(1) prepare, maintain, or submit any records required by or under the Act;

(2) submit any reports required by or under the Act; or

(3) allow any entry, inspection, copying of records, or sampling authorized by the Act.

Section 808(a) would—

(1) revise the prohibition in paragraph (2)(J) of subsection (a) against violations of suspension orders under section 6 to add references to suspension orders under sections 3(c)(2)(B) and new 3A (to be added to the Act by section 105(a) of the bill); and

(2) revise paragraph (2)(K) of subsection (a) (which currently prohibits violations of "any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1)") so that it would prohibit violations of "any cancellation order issued under this Act"; and

(3) with respect to the prohibition against falsification of records under paragraph (2)(M) of subsection (a), change a reference to records maintained "under section 8" to records maintained "under this Act".

Section 808(a) also would add new subparagraphs (R), (S), and (T) to paragraph (1) of subsection (a) to add three new prohibitions, as follows:

(1) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, and submitted to the Administrator, or that the person knows will be furnished

to the Administrator or will become a part of any records required to be maintained by the Act.

(2) To submit data known to be false to the Administrator in support of a registration.

(3) To violate any regulation issued under section 3(a), 19(a), 25(c)(3), or 25(f) of the Act.

Section 3(a), as amended by sections 802(b) and 901(a) of the bill, will authorize the Administrator to regulate the sale, distribution, and use of unregistered pesticides. Section 19(a) establishes procedures for the disposal and transportation of pesticides. Section 25(c)(3) authorizes the Administrator to establish pesticide packaging standards. Section 25(f), to be added by section 815, will provide for a worker health and safety program.

Section 808(b) would amend section 12 of the Act by adding a new subsection (d) to provide that, when construing and enforcing the provisions of the Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person will be deemed to be the act, omission, or failure of the employer as well as that of the person employed.

This provision currently is found in paragraph (4) of section 14(b) of the Act. Section 808(b) would repeal paragraph (4) of section 14(b) to reflect the placement of the provisions in section 12.

Section 809—Penalties.

Section 809(a) would amend subsection (a) of section 14 of the Act, which provides civil penalties for violations of the Act. The amendment would revise paragraphs (1) and (2) of subsection (a) to increase penalties, provide penalties for subsequent violations, and conform subsection (a) to other changes to the Act to be made by the bill.

As revised, paragraphs (1) and (2) will provide that—

(1) any registrant, applicant for a registration, or pesticide testing facility that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If the registrant, applicant for a registration, or pesticide testing facility violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator may assess a civil penalty of not more than $50,000 for each subsequent violation (new paragraph (1));

(2) any commercial applicator of restricted use pesticides, or any other person (not including a registrant, applicant for a registration, or pesticide testing facility) who distributes or sells pesticides or devices that violates any provision of the Act could be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If the person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator could assess a civil penalty of not more than $20,000 for the subsequent violation (new paragraph (1)); and

(3) any private applicator who violates any provision of the Act subsequent to receiving written warning from the Administrator or following a citation for a prior violation and any other person not described in item (1) or (2) above that violates any provision of the Act could be assessed a civil penalty by

the Administrator of not more than $1,000 for each offense. If the person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator could assess a civil penalty of not more than $2,000 for the subsequent violation (new paragraph (2)).

Section 809(a) also would add a new provision to paragraph (2) to authorize the Administrator to waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused significant harm to health or the environment (NOTE: A provision currently in paragraph (2) specifically applicable to pest control operations would be deleted by section 809(a).)

Section 809(a) would amend paragraph (3) of section 14(a), regarding hearings to assess civil penalties, to provide that if a person neither resides nor has its principal place of business in the United States, the Administrator could designate a site for the hearing in the United States that is reasonably convenient for the parties.

Section 809(a) would amend paragraph (4) of section 14(a) to require the administrator, in determining the amount of civil penalty, to consider the economic benefit (if any) gained by the violation of the Act.

Section 809(b) would amend paragraph (1) of section 14(b) of the Act, which provides criminal penalties for violations of the Act by persons (except private applicators) in the pesticide industry. The amendment would increase some penalties and conform paragraph (1) to other changes in the Act made by the bill.

As revised, paragraph (1) would provide that any registrant, producer, or pesticide testing facility that knowingly violates any provision of the Act will be fined not more than $50,000 or imprisoned for not more than 2 years, or both. Any commercial applicator of a restricted use pesticide, or other any person (not including a registrant, producer, or pesticide testing facility) who distributes or sells pesticides or devices that knowingly violates any provision of the Act will be fined not more than $25,000 or imprisoned for not more than 2 years, or both.

Section 899(b) also would amend paragraph (2) of section 14(b) of the Act to increase the maximum penalty for the knowing violation of the Act by a private applicator or other person not covered by paragraph (1) from $1,000 to $2,000, and increase the possible term if imprisonment from 30 days to 60 days.

Section 809(c) would amend section 14(a) of the Act by adding a new paragraph (6) to authorize the Administrator, in connection with administrative proceedings under the civil penalties provisions of the Act, to issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and to request the Attorney General to bring an action to enforce a subpoena. The district courts of the United States would have jurisdiction to enforce the subpoenas and impose sanctions.

Section 810—Congressional review

Section 810 would rewrite paragraph (4) of section 25(a) of the Act, which provides for review by Congress of rules and regulations issued under the Act. Current provisions, which provide for congressional veto of rules and regulations, would be deleted. As rewritten, paragraph (4) will provide that the Administrator, simultaneously with the promulgation of any rule or regulation under the Act, must transmit a copy to the Secretary of the State and the Clerk of the House of Representatives. The rule or regulation would not become effective until 60 calendar days after the rule or regulation is transmitted.

Section 811—Review of regulations

Section 813 would amend section 16 of the act (administrative procedure and judicial review) by adding a new subsection (e) to prescribe the exclusive procedures for the review of regulations issued under the Act.

Paragraph (1) of new subsection (e) provides that any regulation issued under the Act and first published in the Federal Register in final form after the effective date of the bill or any refusal of a petition to modify or rescind a regulation issued under the Act will be reviewable only as provided in subsection (e). Any person could obtain judicial review of the regulation or the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review of a regulation must be filed within 120 days after the date of promulgation of the regulation as determined by the Administrator in the Federal Register. Any such petition for review of a refusal to modify or rescind a regulation must be filed within 120 days after the refusal. In either case, the scope of review would be as specified in section 706 of title 5, United States Code. Section 706 of title 5 provides that

> To the extent necessary to decision and when presented, the review shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—
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> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

The commencement of proceedings under subsection (e) would not, unless specifically ordered by the court to the contrary, operate as a stay of the regulation.

Under paragraph (2) of new subsection (e), regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under the Act would not be subject to judicial review (1) in any suspension, cancellation, or denial proceeding under the Act or in any appeal therefrom, or (2) in proceedings or appeals under section 13 (stop sale, use, removal, and seizure) or 16 (penalties) of the Act, or under subsection (c) of section (b) (district court actions to enforce and to restrain violations of the Act), except on request of an agricultural producer who is adversely affected by the action.

Under paragraph (3) of new subsection (e), if a person who is a party to a proceeding described above that is based on a regulation issued under the Act petitions the Administrator to modify or rescind the regulation, the application of the regulation in the proceeding must be stayed until the Administrator issues a final decision on the petition.

Paragraph (4) of new subsection (e) defines the term "agricultural producer", as used in subsection (e), to mean a nongovernmental producer of agricultural commodities who (1) uses or supervises the use of any pesticide for the production of such commodities on property he or his employer owns or rents, or (2) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the other person's land.

Section 812—Delegation and cooperation

Section 812 would amend section 22 of the Act (delegation and cooperation) by adding a new subsection (c) to provide that the Administrator, in exercising any authority under the Act, will not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that the exercise of authority by the Administrator under the Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1). To ensure the safety and health of workers, the Administrator and the Secretary of Labor must seek to reach agreements and to coordinate the exercise of their statutory authority.

Section 4(b)(1) provides that provisions of the Occupational Safety and Health Act do not apply to working conditions of employees with respect to which other Federal agencies exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

The purpose of section 4(b)(1) is to provide duplication of effort among Federal agencies charged with the protection of workers' safety and health. New subsection (c) would retain the principle of 4(b)(1) while making it clear that the Department of Labor and the

Environmental Protection Agency should enter into agreements to clarify their respective exercise of statutory authority.

Section 813—Indemnity report by EPA

Section 813 would amend section 15 of the Act (indemnities) by adding a new subsection (c). Paragraph (1) of new subsections (c) would require the Administrator, if he has taken an action that requires the payment of indemnification, to report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate—

(1) the action taken that requires the payment of indemnification;

(2) the reasons for taking the action;

(3) the estimated cost of the payment;

(4) the effect the payment would have on the budget of the Administrator to implement the Act without a specific additional appropriation for the payment; and

(5) a request for the appropriation of funds for the payment.

Paragraph (2) of new subsection (c) would prohibit the Administrator from making payments under paragraph (1) unless a specific line item appropriation of funds had been made in advance for the payment.

Section 814—Ground water authority

Section 814(a) would amend section 2 of the Act by adding new definitions to section 2.

New subsection (11) of section 2 defines the term "drinking water well" to mean a well or spring currently supplying water for human consumption.

New subsection (mm) of section 2 defines the term "ground water" to mean water below the land surface in a zone of saturation.

New subsection (nn) of section 2 defines the term "ground water sampling point" to mean a public or community water supply, a private water supply, a spring, or a monitoring well or other ground water source if the well or source is reasonably designed and of adequate depth to permit the collection of representative ground water samples.

New subsection (oo) of section 2 defines the term "potential drinking water" to mean the portion of an aquifer or aquifer system that contains sufficient quantity and is of sufficient quality to supply drinking water to a drinking water well, taking into account (1) geographic considerations and depth to drinking water; (2) any State criteria or guidelines for siting new wells established under section 1428 of the Public Health Service Act (42 U.S.C. 300h et seq.) or other State authority; and (3) shallow ground water that is not potential drinking water.

New subsection (pp) of section 2 defines the term "reliable analytical data" to mean scientific information that verifies the presence of a pesticide in a ground water sample and that is of a reliable scientific quality according to generally recognized standards and good laboratory practices for sampling and analysis of pesticides in ground water.

Section 814(b)(1) redesignates section 31 of the Act as section 32.

Section 814(b)(2) inserts a new section 31 relating to the protection of ground water. It is the intent of the Committee that the ground water protection provisions authorize and require the EPA Administrator to take appropriate regulatory action to protect health and the environment from pesticides in ground water. The ground water provisions apply not only to a pesticide's active ingredient or ingredients, but also, as necessary to protect the public health and environment, to its inert ingredients, and the metabolites and degradation products of the active and inert ingredients. Thus, regulatory provisions of new section 31 referring to a pesticide or its registration may apply to the presence of any one of these substances by itself in ground water as a result of use of the pesticide.

It is also the intent of the Committee that, pursuant to the ground water protection provisions, the Governor of each State should notify EPA regarding the State agency, agencies, or interagency group that will have responsibility for carrying out activities under new section 31.

Subsection (a) of new section 31 would require registrants to notify by report the Administrator, the Governor in each State where the pesticide has been detected, and the owner, if known, of the property at the ground water sample point, of reliable analytical data regarding the detection of a pesticide in ground water within 15 working days. It is the intent of the Committee that this notification requirement applies to information which a person possesses or of which he knows. It is not intended to compel searches for information or extraordinary efforts to acquire information. "Known" information would include information which a prudent person similarly situated could reasonably be expected to know. Negligence or intentional avoidance of information would not absolve a person of this obligation.

The report must contain information known to the registrant on the level of detection, frequency of detection, location, date, well construction, soil type, and analytical method used, including information on the precision, accuracy, and limit of detection of the method, and any quality assurance and control procedures.

Subsection (b) of new section 31 requires the Administrator to promptly review reported information regarding detection of a pesticide in ground water to determine the reliability of the detection and whether further action should be taken.

Subsection (c)(1) of new section 31 provides authority for the Administrator to require registrants to conduct ground water monitoring if he determines that additional data on the presence of the pesticide are required to maintain in effect an existing registration of the pesticide.

The Administrator must consult with the Secretary of Agriculture, the heads of other appropriate Federal agencies, and Governors concerning the design and scope of monitoring requirements imposed under paragraph (1) of new section 31. The design and the scope of the monitoring requirement should take into account information such as the magnitude and frequency of the detection, pattern of pesticide use and soil types involved in the detection, physical, and chemical properties of the pesticide, rainfall patterns, well construction, rates of degradation, reliability and analytical accuracy of the detection, and results of State or other sponsored monitoring.

To the extent feasible, monitoring should be conducted at representative geographical and hydrogeological areas associated with locations and conditions of concern as determined by the Administrator.

Subsection (c)(2) of new section 31 provides that monitoring requirements imposed under subsection (c) of new section 31 would be subject to judicial review under section 16 of the Act.

Subsection (d) of new section 31 requires the EPA under specified conditions to issue Ground Water Residue Guidance Levels (GRGLs) to guide regulatory action.

Paragraph (1) of new subsection (d) requires the Administrator to issue GRGLs when the Administrator registers or reregisters a pesticide that the Administrator determines has potential to leach into ground water. In addition, the Administrator must issue a GRGL if (A) based on reliable analytical data, the pesticide has been detected at sampling points in three different geographical areas (the Committee does not intend this requirement to require detection in three different regions of the country before a GRGL must be issued), (B) based on reliable analytical data, the pesticide has been detected in a drinking water well or well field (which the Committee intends would include a group of wells collectively supplying drinking water) that serves a population of over 10,000 people, or (C) a Federal agency or a State petitions EPA to set a GRGL.

Paragraph (2) of new subsection (d) describes the standards for determining the GRGL. If the Administrator has promulgated a maximum contaminant level (MCL) for the pesticide under the Public Health Service Act, then the GRGL is set at the level within 30 days. If the Administrator has not promulgated a MCL, then the Administrator may use a health advisory level as a basis for setting the GRGL. In addition, the Administrator is required to take into account the level of the pesticide in drinking water at which no known or anticipated adverse effects on the health of persons may occur, the need for an adequate margin of safety, the nature of the toxic effects caused by the pesticide, and the validity, completeness, and adequacy of data about the pesticide. Additional guidance is provided for situations where required chronic, oncogenicity, reproduction, or teratogenicity data are entirely or partially absent or invalid.

Paragraph (3) of new subsection (d) provides for the publication of an interim GRGL within 30 days after the requirement takes effect. This is followed by a 30-day public comment period. During the comment period, the Administrator must invite comment on the proposed GRGL from the Secretary of Agriculture, the Scientific Advisory Panel, and the appropriate congressional committees. Within 3 months of issuing an interim GRGL the Administrator must issue the final GRGL.

Paragraph (4) of new subsection (d) provides that the Administrator may revise the GRGL after a 30 day public comment period.

The Committee intends that the Administrator revise the GRGL if an MCL for the pesticide is promulgated or modified which differs from a GRGL that has been established for the pesticide.

Paragraph (5) of new subsection (d) provides for judicial review of GRGLs under section 16. No judicial review is provided for GRGLs issued under subparagraph (2)(A) of new subsection (d) based upon MCLs, since judicial review for MCLs is provided for under the Public Health Service Act. An interim GRGL would not be subject to judicial review until 3 months after its issuance.

Subsection (e) of new section 31 addresses situations in which a pesticide as a result of normal product use is present in a drinking water well at a concentration that exceeds the GRGL and provides for a site specific response.

Paragraph (1) of new subsection (e) provides that if the Administrator determines that a pesticide is present in a drinking water well at a level higher than the GRGL, then the Administrator must notify the Governor of the State in which the well is located and supply the Governor with all information relevant to the determination. The Governor is then required to take appropriate action within 90 days to bring and retain the concentration of the pesticide in the drinking water well at or below the GRGL or to prevent consumption of drinking water exceeding such level. The Committee intends that the Governor take action within 90 days, but not necessarily to have brought the concentration of the pesticide in the well to or below the GRGL within the specified time.

Paragraph (2) of new subsection (e) provides that after January 1, 1989, if a GRGL is exceeded in a drinking water well, if a State does not have authority or fails to exercise its authority, and if the presence of the pesticide may be the result of use in accordance with the labeling or of widespread and commonly recognized practice, then the Administrator must issue an order prohibiting use of the pesticide in the vicinity of the drinking water well or take such other site specific actions under the Act as the Administrator considers necessary, to meet the requirements of paragraph (1) of new subsection (e) with respect to the drinking water well. Paragraph (2) also provides that any person adversely affected by an action or failure to act by the Administrator under paragraph (2) may petition the Administrator to modify or terminate such action on certain grounds. These hearing procedures are applicable only to actions of the Administrator. Any challenge to the action or inaction of a State should instead be through appropriate administrative or judicial review directed at the State.

Paragraph (3) of new subsection (e) provides that judicial review of actions taken under subsection (e) would be governed by section 16 of the Act.

Paragraph (1) of new subsection (f) requires the Administrator to require registration amendments as a preventive tool to keep pesticides from exceeding the GRGLs in drinking water wells or potential drinking water if, after reviewing reliable analytical data, the Administrator determines there is a reasonable likelihood that the GRGL for a pesticide will be exceeded in drinking water wells or potential drinking water in different localities. These registration amendments shall be those reasonably necessary to ensure that the use of the pesticide will not cause the GRGL to be exceeded.

The Committee intends that the following factors should be considered by the Administrator in determining whether the "reasonable likelihood" test has been met:

(1) The concentration detected relative to the ground water residue guidance level. There shall be a presumption that pesticides detected above 25% of the ground water residue guidance level meet the "reasonable likelihood" standard, unless the other factors described in (2) below lead EPA to determine that the "reasonable likelihood" standard has not been met.

(2) The circumstances surrounding the presence of the pesticide in ground water, taking into account all relevant information, including the frequency and time of occurrence at the site of detection and elsewhere, use patterns, soil types, physical and chemical properties of the pesticide, rainfall patterns, well construction, analytical accuracy, and rates of degradation.

In requiring registration amendments to protect potential drinking water, the Administrator is required to take into account information submitted by the States on land and ground water use classification or other governmental actions which could affect when ground water may be used for drinking water and consider the views of the Secretary of Agriculture, other appropriate Federal agencies (such as the U.S. Geological Survey), and Governors, when the Administrator proposes registration amendments for the purpose of protecting potential drinking water.

Paragraph (2) of new subsection (f) requires the Administrator in making these registration amendments to consult with the Secretary of Agriculture and the Governor of each State involved. The States are required to provide the Administrator with information relevant to taking action under new section 31 and are required to make recommendations regarding necessary registration amendments with respect to the State.

Paragraph (3) of new subsection (f) describes, but does not limit, the types of registration amendments that the Administrator may require.

These amendments may include:

(i) limitations on the purposes for and location at which the pesticide may be used, considering factors such as environmentally sensitive areas and condition;

(ii) limitations on the rate at which the pesticide is applied;

(iii) limitations on the time or frequency of pesticide use;

(iv) limitations on the method of pesticide application, storage, handling, or disposal;

(v) reporting or other requirements, including label changes or changes in classification;

(vi) requirements for the training or certifications of pesticide applicators or other persons using the pesticide;

(vii) required site specific responses; or

(viii) any other requirement under this Act to ensure that the application ground water residue guidance level will not be exceeded.

The amendments to the registration of a pesticide would, to the extent feasible, be directed to the same or similar use of pesticide, geographical and hydrogeological areas and other conditions that led to the determination under subparagraph (A) or (B) of paragraph (1) of new subsection (f). Paragraph (3) also authorizes the Administrator to utilize State recommendations on registration amendments. It further requires the Administrator, in requiring amendments, to consider voluntary actions by registrants or other persons, including actions by the State, to prevent the GRGL from being exceeded, and compliance with other environmental laws.

(Where appropriate, registration amendments may be imposed through the informal rulemaking procedures established under amendments to other provisions of the Act. Nothing in this subsection, including whether a GRGL has been exceeded, is intended to limit or affect the Administrator's separate authority under FIFRA, including initiating suspension or cancellation actions under section 6.)

Subsection (g) of new section 31 provides that the Administrator may collect and make information concerning the detection of pesticide in ground water available through a public information file.

Subsection (h) of new section 31 requires the Administrator to provide technical information to the States to assist in implementing the provisions of new section 31.

Subsection (i) of new section 31 authorizes the Administrator to initiate a public interim administrative review under section 3(c)(8) of the Act when a pesticide has been detected above the GRGL not in a drinking water well or potential drinking water to determine whether the pesticide may cause unreasonable adverse effects on the environment.

Subsection (j) of new section 31 provides that nothing in new section 31 will limit the authority of the Administrator or of any State under other provisions of this Act or any other law. The Committee intends that new section 31 is in addition to and not a substitute for the Administrator's authority to regulate pesticide use with respect to ground water under this Act.

Section 814(c) amends section 12(a)(2) of the Act to add a new subsection (U) providing that it would be an unlawful act to violate an order issued under paragraph (2) of new subsection (e).

Section 815—Worker health and safety

Section 815(a) would amend section 25 of the Act (authority of the Administrator) by adding a new subsection (f) relating to worker health and safety.

Paragraph (1) of new subsection (f) would require the Administrator, as soon as practicable, to promulgate regulations that require the protection, as appropriate and necessary, of (1) *Employees who mix, load, or apply pesticides* and (2) *agricultural employees who work in pesticide treated areas.* The Administrator must promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement established by the Administrator would not apply to any person who is required to receive the training under new subsections (d) and (e) of section 4 of the Act (to be added by section 601(b) of the bill). The term "employees", as used in paragraph (1), would not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

Under paragraph (2) of new subsection (f), the Administrator must promulgate the regulations that require the protection, as appropriate and necessary, of employees (other than *agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas*) not later than three years after the date of enactment of the bill.

The Administrator must provide six months for comments on the proposed regulations to be issued under paragraph (1) that apply to agricultural employees who mix, load or apply pesticides or who work in pesticide-treated areas, and promulgate these regulations not later than two years after the date of enactment of the bill.

Paragraph (3) of new subsection (f) provides that, not later than six months after the date of the publication of the notice of proposed rulemaking issued for the regulations (described in the preceding paragraph) on agricultural employees who mix, load, or apply pesticides or work in pesticide-treated areas, the Secretary of Agriculture must submit to the Administrator a report on the impact, cost, and effectiveness of the regulations on the agricultural community, and submit a copy of the report to Congress.

Paragraph (4) of new subsection (g) would require the Administrator to transmit, simultaneously with promulgation, a copy of the regulations issued under paragraph (1) to the Secretary of the Senate and the Clerk of the House of Representatives. The regulations would not become effective until 120 days after the date the regulations are transmitted. (NOTE: It would be an unlawful act to violate these regulations under section 12 of the Act, as amended by section 809(a) of the bill.

New subsection (g) will create a mandatory duty for the Administrator to issue regulations to (1) protect employees who mix, load, and apply pesticides and agricultural employees who work in pesticide-treated areas, and (2) train employees who mix, load, and apply pesticides. The content and scope of such regulations will be determined by the Administrator as deemed appropriate and necessary. One intent of this subsection is to provide statutory direction to the Environmental Protection Agency to proceed with its current efforts to issue farmworker regulations. This subsection is not intended to alter the content or scope of the farmworker regulations under review by EPA.

The EPA must continue to develop and maintain expertise on working conditions and practices of workers exposed to pesticides and use this expertise for such activities as evaluating registration, reregistration, public interim administrative review, and cancellation decisions with respect to effects of such actions on worker health and safety.

Section 816—Authorization for appropriations

Section 816 would amend section 33 of the Act (as redesignated by section 202(b) of the bill), effective October 1, 1986, to authorize to be appropriated to carry out the Act (other than sections 23(a) and 31) $78,363,500 for fiscal year 1987, of which not more than $13,735,500 must be available for research under the Act, $87,414,200 for fiscal year 1988, of which not more than $14,343,600 must be available for research under the Act, $91,673,400 for fiscal year 1989, of which not more than $14,978,200 must be available for research under the Act, $98,305,800 for fiscal year 1990, of which not more than $15,625,900 must be available for research under the act, and $106,808,700 for fiscal year 1991, of which not more than $16,300,100 must be available for research under the Act.

Section 817—Neurotoxic and behavioral effects of pesticides

Section 817 amends section 3 of the Act by adding a new subsection (h) relating to neurotoxic and behavioral effects of pesticides.

Paragraph (1) of new subsection (h) requires the Administrator to conduct and support such research as the Administrator finds appropriate to develop methods for testing to more accurately detect neurotoxic and behavioral effects of pesticides and the ingredients of pesticides.

Paragraph (2) of new subsection (h) requires the Administrator, as such methods are developed, to require that data from such testing be submitted by persons seeking to obtain or maintain pesticide registrations under the Act, to the extent appropriate and necessary.

Section 818—Pesticide Containers

Section 818(a) amends section 19 of the Act by adding new subsections relating to pesticide containers.

Paragraph (1) of new subsection (d) provides that not later than 3 years after the effective date of the bill, Administrator must in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides. The regulations must assure, to the fullest extent practicable, that the containers—

(i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers;

(ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from the containers;

(iii) facilitate the safe disposal of the containers; and

(iv) facilitate the safe refill and reuse of the containers.

Paragraph (2) of new subsection (e) requires the Administrator to require compliance with the regulations referred to in paragraph (1) of new subsection (d) not later than 5 years after the effective date of the bill.

Paragraph (1) of new subsection (e) requires the Administrator not later than 3 years after the effective date of the bill in consultation with the heads of other interested Federal agencies, to promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal. The regulations may—

(i) specify, for each major type of pesticide container, procedures and standards providing for, at a minimum, triple rinsing or the equivalent degree of pesticide removal;

(ii) specify procedures that can be implemented promptly and easily in various circumstances and conditions;

(iii) provide for reuse, whenever practicable, or disposal of rinse water and residue; and

(iv) be coordinated with requirements for the rinsing of containers imposed under the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.).

The Committee believes that requirements regarding disposal or reuse should appear on the pesticide lable. The procedures for making label changes by rulemaking should be used whenever appropriate to specify these procedures and standards.

Paragraph (2) of new subsection (e) provides that effective beginning 5 years after the effective date of the bill, a State may not exercise primary enforcement responsibility under section 26 of the Act, or certify an applicator under section 4 of the Act, unless the Administrator determines that the State is carrying out an adequate program to assure compliance with new subsection (e).

Regulations developed under this section are to more clearly specify residue removal procedures and are not intended to substantively expand existing authorities.

Paragraph (1) of new subsection (f) requires the Administrator to conduct a study of options to encourage or require—

(i) the return, refill, and reuse of pesticide containers;

(ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and

(iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

In conducting the study, the Administrator must consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations; and assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures of actions.

Paragraph (2) of new subsection (f) requires the Administrator not later than 2 years after the effective date of the bill to submit to Congress a report describing the results of the study required under paragraph (1) of new subsection (f).

Section 818(b) amends section 2 of the Act by adding a new subsection (qq) defining the term "container" to mean any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding spray applicator tanks) used to enclose a pesticide or pesticide-related waste.

Subtitle B—Other Provisions

Section 821—Liability

Section 821 provides that—

(1) an agricultural producer will not be liable in any action brought after the effective date of the bill, under any Federal statute, for damages caused by pesticide use unless the producer has acted negligently, recklessly, or intentionally. Proof that an agricultural producer used a pesticide consistent with label instructions will create a rebuttable presumption that the agricultural producer did not act negligently;

(2) nothing in section 821 may be construed as conferred a private right of action on any person for purposes of this Act or any other Federal law.

(3) for the purposes of these provisions, the term "agricultural producer" means a nongovernmental producer of agricultural commodities who uses or supervises the use of any pesticide for the production of the commodities on property owned or rented by him or his employer, or who without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the other producer's land; and includes the producer of, among other things, a food, feed, or fiber commodity, livestock, poultry, fruit, vegetable, tobacco, or forestry, ornamental, nursery, or horticultural commodity or product raised, grown, or produced for a commercial purpose.

Section 822—IR-14 program

Section 822 would amend section 2(c) of the Act of August 4, 1965, relating to agricultural research grants, to require the Secretary of Agriculture to provide support under such Act for the interregional project number 4 program (commonly referred to as the "IR-4 program"), which generates health and safety data on minor use pesticides that are used for agricultural purposes.

Section 823—Pesticide risk rating

Section 823 would authorize the Administrator to contract with the Board of Agriculture of the National Academy of Sciences to conduct a study to determine the feasibility of establishing an environmental risk rating for pesticides used in the production of agricultural commodities. The risk rating must take into consideration methods of application, chronic and acute toxicity, and anticipated losses to and persistence in the environment. In conducting the study, the National Academy of Sciences must seek information and advice from recognized public and private sector scientists and provide opportunity for public comment on the preliminary findings relating to the development of a risk rating.

The National Academy of Sciences must report the findings of the study to the Administrator and to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate within 18 months after the date of the enactment of the bill. The risk rating study must be conducted at the cost established by the Administrator, in consultation with the National Academy of Sciences. The authority of the Administrator to enter into contracts under section 823 would be effective only to such extent or in amounts as are provided in advance in appropriation Acts.

TITLE IX—CLARIFYING AND TECHNICAL AMENDMENTS

Section 901—Clarifying amendments

Section 901(a)(1) would add a new provision to subsection (a) of section 3 of the Act, which contains one sentence to be revised by section 802(b) of the bill to prohibit the distribution or sale of an unregistered pesticide (current law has essentially the same provision). The added provision provides that, to the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under the Act and that is not the subject of an experimental use permit or an emergency exemption.

Section 901(a)(2) would amend section 3(c)(7)(A) of the Act to clarify that an applicant seeking conditional or amended registration may cite as well as submit required data.

Section 901(a)(3) would amend section 3(d) of the Act to clarify that pesticides may be reclassified by regulations, and to clarify the Administrator's authority to regulate the use of restricted pesticides.

Section 901(b) would amend section 4 of the Act (certified applicators) to clarify the Administrator's authority to issue regulations under that section of the Act.

Section 901(c) would amend section 7(c) of the Act (registration of pesticide production or distribution establishments) to clarify the Administrator's authority to issue regulations describing information and reports to be supplied under section 7 of the Act.

Section 901(d) would amend section 25(c) of the Act (specified authorities of the Administrator) to clarify that the Administrator may issue regulations to carry out the authority provided in that section of the Act.

Section 902—Technical amendments

Section 902 would make clerical, conforming, and other technical amendments to the Act.

Section 902—Table of contents amendments

Section 903 would make amendments to the table of contents of the Act to conform with the amendments to the Act made by the bill.

TITLE X—EFFECTIVE DATE

Section 1001—Effective date

Section 1001 provides that, except as where otherwise specified by the bill, the amendments to the Act made by the bill will take effect on the expiration of 60 days after the date of enactment of the bill.

COST ESTIMATE

I.

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the Committee estimates the cost of carrying out the bill as follows:

Estimated outlays for fiscal year:	*Millions*
1987	$58
1988	84
1989	96
1990	104
1991	113

II.

In accordance with the Congressional Budget Act of 1974, the Congressional Budget Office prepared the following cost estimate:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 3, 1986.

Hon. JESSE A. HELMS,
Chairman, Committee on Agriculture, Nutrition, and Forestry,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,

Sincerely,

EDWARD GRAMLICH
(For Rudolph G. Penner, Director).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: Not yet assigned.

2. Bill title: Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

3. Bill status: As ordered reported by the Senate Committee on Agriculture, Nutrition, and Forestry, August 13, 1986.

4. Bill purpose: This bill would amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) by changing numerous procedures used by the Environmental Protection Agency (EPA) to register pesticides, including those related to data gathering, cancellation and enforcement. The bill would mandate a comprehensive process to be used in reregistering substances that had been approved under earlier versions of the act. Also the bill would provide for greater public and state access to pesticide data at various stages of the registration process.

Title I of the bill would provide for reregistration fees to be collected from pesticide registrants when applications and supporting data are submitted. Amounts generated through fees would be deposited into a fund for use by the EPA in carrying out the reregistration program.

Title VIII would authorize appropriations for fiscal years 1987 through 1991 for abatement and control programs carried out under the act and for pesticide research. The bill would authorize separate appropriations of sums necessary to cover 50 percent of the cost to states or Indian tribes of training programs and pesticide certification and licensing.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1987	1988	1989	1990	1991
Estimated authorization level	87	96	101	107	116
Estimated outlays	58	84	96	104	113

The costs of this bill fall within budget function 300.

The table does not include any costs that may be incurred as a result of legal actions arising out of the EPA's disclosure of data to a state. Under Section 202 of the bill, such actions may arise if a state improperly uses data obtained from the EPA. In such situations, defined by the bill to involve a taking of property, all state actions shall be deemed to be actions of the federal government. As in any situation involving potential costs to satisfy legal claims that may or may not arise in the future, it is not possible to estimate the likely budgetary impact of Title II. However, if successful claims do arise, the cost to the federal government could be significant.

Basis of Estimate:

For the purpose of this estimate, it is assumed that the full amounts authorized will be appropriated for each fiscal year.

Authorization levels for 50 percent matching grants to states and Indian tribes have been estimated on the basis of information obtained from the EPA. The total cost to the states of carrying out training and certification/licensing activities required under the act, as amended by Title XVI of this bill, is estimated to be about $18 million a year. If the EPA is to be able to enter into cooperative agreements specifying a federal/state cost share of 50/50, approximately $9 million would have to be apropriated each year. Currently, about $2.5 million per year is appropriated for these grants.

Outlays for pesticide programs, grants, and data systems development have been estimated on the basis of historical spending patterns for similar activities.

6. Financing mechanism: Most of the programs authorized by this bill would be funded through authorizations that would be subject to subsequent appropriation acts. However, Title I of the bill would create direct spending of an estimated $5 million a year. This direct spending would be funded through offsetting collections that the EPA would be required to collect from reregistration applicants. CBO estimates that these collections would total about $45 million over nine years, or $5 million a year through fiscal year 1995.

7. Estimated cost to State and local governments: Title VIII would require states, when notified by the EPA of pesticide contamination in a well, to take appropriate action to reduce the pesticide level or prevent the consumption of contaminated water. Such action would be required in cases in which a properly applied and commonly used pesticide has been involved. The implications of this provision for the budgets of state governments is uncertain. If Title VIII is interpreted to require that states take steps to treat

contaminated groundwater or to provide alternative drinking supplies, the cost could be great. If a more narrow interpretation is adopted, states may still incur significant administrative and enforcement costs related to issuing the necessary prohibitions against pesticide use or drinking water consumption. CBO has not completed its analysis of this issue and will submit a more detailed analysis at a later date.

Title VI would impose new requirements on states relating to their training and certification/licensing programs. Under current law, states spend at least $5 million per year on these activities, about $2.5 million of which is recovered through federal matching grants. The requirements in Title VI are expected to result in additional costs to states of about $13 million, one-half of which would be recovered through federal matching grants, assuming appropriation of the necessary sums.

8. Estimate comparison: None.

9. Previous CBO estimate: On July 14, 1986, the Congressional Budget Office prepared a cost estimate for H.R. 2482, a similar bill ordered reported by the House Committee on Agriculture. The slight differences in the estimated costs of the two bills reflect different authorization levels.

10. Estimate prepared by: Deb Reis.

11. Estimate approved by: E.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

REGULATORY IMPACT EVALUATION

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following evaluation of the regulatory impact that would be incurred in carrying out the Committee bill.

The bill would effect major changes in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), particularly with regard to the pesticide registration and Special Review process, regulation of inert ingredients in pesticide products, protection of ground water, and applicator certification and training.

(a) Description and estimated numbers of individuals and businesses to be regulated—

1. Pesticide producers, formulators and dealers.

The pesticide producing industry of the United States consists of about 30 major manufacturers of active ingredients, along with 100 smaller producers and 3,300 formulators. In a typical year, 200 to 400 new firms register for the first time with the Environmental Protection Agency (EPA) as pesticide manufacturers or formulators.

There are approximately 29,500 distributors and registered establishments through which pesticides flow in the United States. These various marketing units and establishments are regulated under enforcement programs of FIFRA. Within this group are about 15,000 to 20,000 dealers which would be expected to sell restricted use products.

2. States.

Under FIFRA, the States are EPA's partners in pesticide regulation. All the States would be affected by the certification and training and ground water provisions of the bill.

3. Pesticide applicators/users.

Pesticides are used on a majority of 2 million farms and 75 million households in the United States each year. In addition, there are several million industrial, commercial and governmental users of pesticides in the United States, all of which are subject to at least some form of regulation and/or training program under FIFRA.

The amendments affect certified commercial applicators, registered commercial applicators, certified private applicators and supervised private applicators, along with businesses which employ commercial applicators. (Registered commercial applicators and supervised private applicators are two new groups which are affected by the proposed amendments.) Approximately 30,000 commercial applicators will be trained and certified each year and approximately 200,000 commercial applicators will need to be trained and registered with the States. Approximately 100,000 private applicators will be trained and certified each year and approximately 2,000,000 supervised private applicators will need to receive training.

Under the proposed amendments, there is a new requirement that Federal and State enforcement personnel receive training in the commercial applicator categories for which they are assigned enforcement responsibility. Approximately 25 Federal enforcement personnel and 200 State enforcement personnel will require training.

(b) Economic impacts on affected individuals and businesses—

In general, the economic impacts of FIFRA implementation fall on basic producer registrants, other registrants, primary formulators, users and State authorities. Presented below is a brief discussion of economic impacts of implementation of the proposed amendments.

1. Pesticide producers.

For basic producers which currently number up to 130 firms, total compliance costs are estimated to be in the range of $160 million industry wide for 1987 under the existing law. There would be significant increases in this baseline cost under the proposed amendments. Basic producer registrants would need to meet new data and other requirements for inert ingredients as well as their active ingredients and formulations. Registrants would incur fees to cover the cost of activities within EPA to reregister active ingredients. There would be additional nominal impacts from additional reporting and recordkeeping requirements in connection with production, distribution, and export of pesticides such as dealing with tolerances and ground water issues. The additional provisions include a requirement for the industry to monitor for ground water residues at some cost and report results of concern to authorities. It is possible that the amendments could increase the cost to basic producers for compliance in the neighborhood of 10–15%, i.e., $16–24 million per year.

The impacts from the proposed amendments on formulators would generally be minor and of limited economic consequences.

They could be impacted by provisions dealing with inert ingredients in instances where the firm had not incurred such costs as a result of also being a producer of the basic active ingredient. There would not be expected to be more than a 5% increase in costs of compliance for the 3,300 formulators i.e., about $2.5 million per year.

Under the bill dealers supplying restricted use pesticide products would have recordkeeping requirements not required by the present law. It is possible that record requirements could involve one hour of personnel time per week resulting in an annual incremental cost of $500 per firm or about $7.75 million nationwide. There would not appear to be any additional compliance costs for the remaining 14,000 distributors and establishments.

2. States.

The cost to the States from the proposed amendments will be approximately $9,000,000. This includes training and certification of applicators, registration of commercial applicators, and prescribing training for applicators and standards for trainers.

3. Pesticide applicators.

The cost to individuals for initial training and certification and registration under the amendments will be approximately $10-20 per person.

4. EPA.

The bill requires EPA to implement a new reregistration program to reregister, over a period of about nine years, pesticides with active ingredients contained in pesticides registered before November 1, 1984. This requirement is both an acceleration of and a substantial change to the current reregistration program. The bill also provides for reregistration fees to help pay for the cost of the expanded program.

Reregistration Costs Under The Bill

	Millions
Program cost	$210-220
Resources available	165
Shortfall	45-55

The bill also would have substantial cost impacts on EPA in several other areas including regulation of inert ingredients, and implementation of new cancellation procedures for Special Reviews, and extended applicator certification and training program, and new ground water response provisions.

(c) Impacts on personal privacy—None.

(d) Additional paperwork burden likely to result—Base for the current program—4.6 million burden hours.

Inert Ingredients.—Slight to moderate increase over current and anticipated program.

Public Right to Know; Fact Sheet and Annual Report.—Slight increase: chemical and physical properties of active ingredients are already known and provided to EPA.

Public Interim Administrative Review.—No increase over current burden.

False and Invalid Data.—No change.

Uniform Tolerances.—Insignificant burden on States for requesting exemptions for State residue limits.

Exports.—Slight increase in burden due to additional record keeping requirements.

Data Compensation.—No change.

Information Requested.—No change.

Groundwater.—Could be a substantial increase in burden for registrants, particularly for agricultural use pesticides. Would have increased requirements to identify follow through, monitor, and report on potential ground water contaminants.

Health and Safety.—The major burden will be on agricultural chemical users but non-agricultural workers would also be affected. Training and associated record keeping for non-certified applicators could be a major burden and increase. Design and implementation of training requirements will be the major significant burden.

Reregistration.—The paperwork burden for the reregistration proposal has two components—a major acceleration of information requirements and substantial increases in the burden caused by changes from the current process.

The filling of data gaps and identification of adverse data for new studies will cause a major short term increase in the paperwork burden. However, this is a burden which would be levied on the industry under the current process although over a much longer time period. Thus the overall burden from these aspects of the proposed program may not differ substantially from the current program, over the long term.

Several aspects of the proposed program would add to the overall burden. These are:

Registrant identification of missing and inadequate data—moderate increase in overall burden;

Reformatting and summarizing existing data thought to be adequate—moderate increase;

Certification of possession of raw data—slight increase; and

Flagging adverse data for existing studies—slight increase over effort to reformat and summarize.

Each of these tasks adds a slight to moderate increase in the overall burden.

Certification and training

There will be a substantial increase in paperwork for State organizations/agencies responsible for training and certifying pesticide applicators. Such State agencies will be required to train and certify commercial applicators who are not certified, verify training given by private organizations, and reregister and recertify applicators every 5 years.

The increase in paperwork burden for pesticide dealers will be moderate since in general they will be required to keep records of restricted use pesticides which they sell or distribute. Some States already have recordkeeping requirements in place.

ROLLCALL VOTES

In accordance with paragraphs 7(b) and 7(c) of Rule XXVI of the Standing Rules of the Senate, it is announced that—

(1) A motion was offered that, with regard to DataCompensation on Patent Term Restoration, the 17-year patent on a pesticide product should run from the time the product is marketed, and that the compensation for data paid by subsequent registrants to the original data submitter should be based on a fair share of the actual cost of producing the compensable data, plus an amount no greater than that share. The motion was defeated by a vote of 5 to 11 as follows:

YEAS	NAYS
Zorinsky	Lugar
Melcher	Cochran*
Pryor	Boschwitz
Boren	Hawkins*
Andrews*	Wilson*
	McConnell*
	Leahy
	Dixon
	Heflin*
	Harkin
	Helms

*By proxy.

(2) A motion was offered to provide that the findings and determinations of the arbitrator in an arbitration to determine the amount of compensation to be paid by a subsequent registrant to the original data submitter shall be subject to judicial review of the United States Court of Appeals upon the filing of an action by a party to the arbitration, up to the date said person submits such application. The findings and determinations of the arbitrator will be sustained, if they are supported by substantial evidence, when considered on the record of the arbitration as a whole. The motion was approved by a 15 to 1 vote as follows:

YEAS	NAYS
Lugar	Andrews*
Cochran*	
Boschwitz	
Hawkins*	
Wilson*	
McConnell*	
Zorinsky	
Leahy	
Melcher	
Pryor	
Boren	
Dixon	
Heflin*	
Harkin	
Helms	

*By proxy.

(3) A motion was offered to retain current law (regarding tolerances for agricultural commodities) which provides general authority for the Administrator to establish tolerances for pesticide

chemicals in or on raw agricultural commodities. The motion was approved by a 9 to 7 vote as follows:

YEAS	NAYS
Dole*	Leahy*
Lugar	Melcher
Cochran	Pryor*
Boschwitz	Boren
Andrews*	Dixon*
Wilson*	Heflin
McConnell*	Harkin
Zorinsky	
Helms	

*By proxy.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

* * * * * * *

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a)* * *

* * * * * * *

[(b) TABLE OF CONTENTS.— * * *]

(b) TABLE OF CONTENTS.—

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SEC. 2. DEFINITIONS.

For purposes of this Act—

(a) * * *

* * * * * * *

(c) ADULTERATED.—The term "adulterated" applies to any pesticide [if :] *if—*

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

* * * * * * *

[(e) CERTIFIED APPLICATOR, ETC.—

[(1) CERTIFIED APPLICATOR.—The term "certified applicator" means any individual who is certified under section 4 as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

[(2) PRIVATE APPLICATOR.—The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

[(3) COMMERCIAL APPLICATOR.—The term "commercial applicator" means an applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

[(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.]

(e) APPLICATOR.—

(1) COMMERCIAL APPLICATOR.—

(A) Except as provided in subparagraph (B), the term "commercial applicator" means a person (whether or not the person is a private applicator with respect to some uses) who—

(i) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use;

(ii) uses or supervises the use of any pesticide (other than a pesticide that the Administrator determines may be applied without the need for training) for hire as the principal part of the business or work of the person; or

(iii) as an employee of a person described in clause (ii), uses or supervises the use of any pesticide.

(B) The term does not include a person who uses or supervises the use of a pesticide as described in paragraph (2).

(2) PRIVATE APPLICATOR.—The term "private applicator" means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity—

(A) on property owned or rented by such person or the employer of such person; or

(B) on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) CERTIFIED APPLICATOR.—The term "certified applicator" means a commercial or private applicator who is certified under section ii".

(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if the pesticide is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is used.

* * * * * * *

[(n) INGREDIENT STATEMENT.—The term "ingredient statement" means a statement which contains—

[(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

[(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.]

(n) Ingredient Statement.—The term "ingredient statement" means a statement that contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in a pesticide;

(2) the name of each inert ingredient in the pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the toxicity, use pattern, and concentration level of the inert ingredient in the pesticide;

(3) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic;

(4) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented; and

(5) the name of any inert ingredient for which the Administrator has required additional data under section 3(g)(5) because such ingredient is listed under section 3(g)(1)(A) as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under section 3(c)(8).

* * * * * * *

(p) Label and Labeling.—

(1) Label.—The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling.—The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) Accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of **[**Health, Education, and Welfare**]** *Health and Human Services,* State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded.—

(1) A pesticide is misbranded if—

(A) * * *

* * * * * * *

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment; **[**or**]**

(H) in the case of a pesticide not registered in accordance with section 3 of this Act and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America"[.]; *or*

(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label—

(i) is not written in an appropriate language as required by section 17(a)(4)(A); or

(ii) does not contain the same health safety, and hazard precautions as the pesticide registered under section 3, unless such precautions on the label are in conflict with the law of the importing country.

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on the part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph [if:] *if—*

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

* * * * * * *

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) * * *

* * * * * * *

(iii) the net weight or measure of the content[: *Provided,* That], *except that* the Administrator may permit reasonable variations; and

* * * * * * *

(u) Pesticide.—The term "pesticide" means (1) any substance or mixture or substances intended for preventing, destroying, repelling, or mitigating any pest, [and] (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, *and (3) any substance or mixture of substances intended for a purpose described in subsection (gg)* [: *Provided,* That] *except that* the term "pesticide" shall not include any article [(1)(a)] that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)), [or (b)] that has been determined by the Secretary of [Health, Education, and Welfare] *Health and Human Services* not to be a new animal drug by a regulation establishing conditions of use for the article, or [2] that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing or containing [an article covered by clause (1) of this proviso] *a new animal drug.*

* * * * * * *

(bb) Unreasonable Adverse Effects on the Environment.—The term "unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. *For purposes of this subsection, the term "man" includes unborn human beings from the moment of conception.*

* * * * * * *

(ee) To Use Any Registered Pesticide in a Manner Inconsistent With Its Labeling.—The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling[: *Provided,* That], *except that* the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling *unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency,* (2) applying a pesticide against any target pest not specified on the labeling if the application is to crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling *unless the labeling specifically states that the product may be applied only by the methods specified on the labeling,* [or] (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling[: *Provided further,* That the term also shall not include], *(5)* any use of a pesticide in conformance with section 5, 18, or 24 of this Act, or *(6)* any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act[: *And provided further,* That after]. *After* March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding Data Requirement.—

(1) In general.—The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 3(c)(5) and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under sec-

tion 3(c)(5) and the regulations and guidelines issued under such section, as determined by the Administrator.

(2) Factors.—In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) Antimicrobial.—The term "antimicrobial" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air;

(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

(3) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;

(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or

(5) fungicides or fungistats.

(hh) Pesticide Testing Facility.—The term "pesticide testing facility" means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing the pesticide). The term does not include any person solely on account of the participation of such person as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under section 5.

(ii) Importing Country.—The term "importing country" means the first country to which a pesticide, device, or active ingredient, subject to the notification requirements of section 17(a), is exported from the United States.

(jj) Pesticide Dealer.—

(1) In general.—Except as provided in paragraph (2), the term "pesticide dealer" means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or designated under section 8(d)(2).

(2) Exception.—Such terms does not include a person who only distributes or sells pesticides that are classified for general use and that are not designated under section 8(d)(2).

(kk) To Distribute or Sell.—The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by an applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(ll) Drinking Water Well.—The term "drinking water well" means a well or spring currently supplying water for human consumption.

(mm) Ground Water.—The term "ground water" means water below the land surface in a zone of saturation.

(nn) Ground Water Sampling Point.—The term "ground water sampling point" means a public or community water supply, a private water supply, a spring, or a monitoring well or other ground water source if the well or source is reasonably designed and of adequate depth to permit the collection of representative ground water samples.

(oo) Potential Drinking Water.—The term "potential drinking water" means the portion of an aquifer or aquifer system that contains sufficient quantity and is of sufficient quality to supply drinking water to a drinking water well, taking into account—

(1) geographic considerations and depth to drinking water;

(2) any State criteria or guidelines for siting new wells established under section 1428 of the Safe Drinking Water Act (42 U.S.C. 300h-7) or other State authority; and

(3) shallow ground water that is not potential drinking water.

(pp) Reliable Analytical Data.—The term "reliable analytical data" means scientific information that verifies the presence of a pesticide in a ground water sample and that is of a reliable scientific quality according to generally recognized standards and good laboratory practices for sampling and analysis of pesticides in ground water.

(qq) Container.—The term "container" means any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding spray applicator tanks) used to enclose a pesticide or pesticide-related waste.

SEC. 3. REGISTRATION OF PESTICIDES.

[(a) Requirement.—Except as otherwise provided by this Act, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator.]

(a) Requirement of Registration.—Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.

* * * * * * *

(c) Procedure for Registration.—

(1) Statement required.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) * * *

* * * * * * *

(D) except as otherwise provided in [subsection (c)(2)(D) of this section] *paragraph (2)(D),* if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this Act after the date of enactment of the Federal Pesticide Act of 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide[: *Provided,* That such]. *Such* permission shall not be required in the case of defensive data[;].

(ii) [except] *Except* as otherwise provided in [subparagraph (D)(i) of this paragraph] *clause (i),* with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, [or for reregistration,] *for reregistration, or to support the safety of an inert ingredient* the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application *or in support of the safety of an inert ingredient* by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation **[;]**.

(iii)(I) In the case of a pesticide the term of the patent for which has expired, the terms and amount of compensation, for data that was submitted for such pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites such data may be fixed before the submission of such application by arbitration under clause (ii) initiated by such person.

(II) The arbitration shall be binding on the original data submitter and shall be binding on such person after the date the application of such person is submitted.

(III) The findings and determination of the arbitrator shall be subject to judicial review in the United

States Court of Appeals on the filing of an action by a party to the arbitration up to the date such person submits such application. The findings and determination of the arbitrator with regard to issues of fact shall be sustained if they are supported by substantial evidence when considered on the record of the arbitration as a whole.

(IV) Each party to the first arbitration under this clause to determine the terms and amount of compensation for the use of particular data shall share equally in the payment of the fees and expenses of the arbitrators and shall each pay its own attorney's fees.

(V) In all subsequent arbitrations under this clause to determine the terms and amount of compensation for the use of such data, the party to such subsequent arbitration who seeks to cite the data of the original data submitter shall pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter.

(VI) Clause (ii) shall apply to arbitrations under this clause, except as otherwise provided in this clause.

[(iii)**]** *(iv)* **[**after**]** *After* expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under **[**subparagraphs (D)(i) and (D)(ii) of this paragraph**]** *clauses (i), (ii), and (iii),* the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data**[**;**]**.

* * * * * * *

[(2)(A) DATA IN SUPPORT OF REGISTRATION.—The**]**

(2) DATA IN SUPPORT OF REGISTRATION.—(A) The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph *(including information regarding an inert ingredient in a pesticide),* he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make

available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

[(B) ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATION.—

[(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

[(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.]

(B)(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide or the existing registrations of a group of pesticides, the Administrator shall notify the registrant of each pesticide to which the determination relates and provide a list of such registrants to any person.

(ii)(I) Each registrant of such a pesticide shall provide evidence within 90 days after receipt of notification that the registrant is taking appropriate steps to secure and submit the additional data that are required.

(II) Two or more registrants may agree to develop jointly, or to share in the cost of development of, such data. Any registrant who enters into such an agreement, or who offers to agree to share in the cost of development of such data, shall be entitled to examine such data and rely on such data to maintain or obtain registrants under this Act or under the law of any State. An offer to enter into such an agreement may be accepted at any time and may not be withdrawn without the consent of the person to whom the offer was made.

(iii) [If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service.] *If at the end of 60 days after two or more registrants have entered into an agreement under clause (ii) the registrants have not further agreed on the terms of the data development or cost-sharing agreement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings to fix such terms by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from* *the roster of arbitrators maintained by the Service.* The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator.

(iv) Notwithstanding any other provisions of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under the subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph or a registrant failed to take an action required under clause (ii)(II), the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act **[**: *Provided,* That the**]**. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registation of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provisions of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of [subsection (d)(1)(D) of this section.] *paragraph (1)(D).* Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for joint submitters of such data.

* * * * * * *

(C) [SIMPLIFIED PROCEDURES.—] Within nine months after date of enactment of this subparagraph, the Administrator shall by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

[(D) EXEMPTION.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

[(i) submit or cite data pertaining to the safety of such purchased product; or

[(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.]

(D)(i) No applicant for registration or amended registration of a pesticide who proposes to purchase a registered pesticide from another producer to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(I) submit or cite data pertaining to such purchased pesticide; or

(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data.

(ii) No applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study concerning such ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.

* * * * * * *

(4) NOTICE OF APPLICATION.—The Administrator shall publish in the Federal Register, [promptly] *not later than 30 days* after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. [The] *Except as provided in paragraph (9), the* notice shall provide for a period of [30] *60* days in which any Federal agency or any other interested person may comment.

* * * * * * *

(6) DENIAL OF REGISTRATION.—If the Administrator determines that the requirements of paragraph (5) of registration are not satisfied, he shall notify the applicant for registration of his determination and of his reasons (including the factual

basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, he shall notify the applicant of his decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6[.] *except as otherwise provided in this paragraph. A request for a hearing under section 6 shall be made within 30 days after the receipt of such notification. The Administrator may issue regulations governing the right to a hearing under section 6 with regard to the denial of any application for the registration of a pesticide containing an ingredient that was canceled under section 6. Under such regulations, due weight shall be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings. Section 6(g)(2) applies with respect to the publication of a notice of a denial of a registration.*

(7) REGISTRATION UNDER SPECIAL CIRCUMSTANCES.—Notwithstanding the provision of [subsection (c)(5) of this section] *paragraph (5)*—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subpararaph shall submit *or cite* such data as would be required to obtain registration of a similar pesticide under [subsection (c)(5) of this section: *Provided*, That, if] *paragraph (5). If* the applicant is unable to submit *or cite* an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission *or citation* of such data not later than the time such data are required to be submitted *or cited* with respect to similar pesticides already registered under the Act.

[(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provision of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations, issued under this Act, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves as minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section: *Provided,* That, if the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

[(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe: *Provided,* That a conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.**]**

(B)(i) The Administrator may conditionally amend the registration of a pesticide under this subparagraph to permit additional uses of such pesticide notwithstanding the fact that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that—

(I) the applicant has submitted or cited additional data that the Administrator may require solely for the proposed additional use;

(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effects on the environment; and

(III) the additional use is in the public interest.

(ii)(I) Except as provided in subclause (II), if the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), no registration of the pesticide may be amended under clause (i) to add any food or feed use during the pendency of any evaluation by the Administrator initiated by such notice.

(II) If the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), the Administrator may amend the registration of the pesticide under clause (i) to add a minor food or feed use if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is not available an effective alternative pesticide that does not meet or exceed such risk criteria.

(iii) An applicant seeking an amended registration of a pesticide under this subparagraph shall submit or cite to the Administrator such data as would be required to obtain a registration of a similar pesticide under paragraph (5). Except as provided in clause (iv), if the applicant is unable to submit or cite an item of such data because it has not yet been generated, the Administrator may amend the registration of the pesticide under such conditions as will require the submission or citation of such data not later than the time such data are required to be submitted for the maintenance of a registration of the similar pesticide under this section.

(iv) If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide and if a period reasonably sufficient for the generation and submission of such data has elapsed since the Administrator first imposed the data requirement, a conditional amendment to permit an additional use of the pesticide for other than a minor use shall not be granted under clause (i) unless such data have been submitted.

(C)(i) The Administrator may conditionally register a pesticide under this subparagraph containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of required data that have not been submitted because a period reasonably sufficient for generation of the data has not

elapsed since the Administrator first imposed the data requirement--

(I) on the conditions that by the end of such period the Administrator receives such data and that the data that the Administrator receives do not meet or exceed risk criteria enumerated in regulations issued under paragraph (8); and

(II) on such other conditions as the Administrator may prescribe.

(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

(I) use of the pesticide during the period referred to in clause (i) will not cause any unreasonable adverse effect on the environment; and

(II) use of the pesticide is in the public interest.

(iii) The Administrator shall not conditionally register a pesticide under this subparagraph if—

(I) data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of such a pesticide under paragraph (5);

(II) a period reasonably sufficient for generation of such data has elapsed since the Administrator first imposed the data requirement; and

(III) such data have not been submitted to the Administrator.

[(8) INTERIM ADMINISTRATIVE REVIEW.—Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.]

(8) PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

(A) A public interim administrative review process to determine whether the use of a pesticide (including a category of pesticides) may cause unreasonable adverse effects on the environment shall be conducted in accordance with this paragraph.

(B)(i) Criteria for initiating a public interim administrative review of a pesticide shall be set forth in regulations published by the Administrator.

(ii) Such criteria shall be established on the basis of levels of risk and may include consideration of currently available exposure data.

(iii) Absence of exposure data shall not delay or preclude initiation of a public interim administrative review. The Administrator may decline to initiate a public interim ad-

ministrative review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

(C) The Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of such pesticide required under this Act unless such public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

(D)(i) On receipt of information respecting a pesticide demonstrating that the criteria for initiating a public interim administrative review established under subparagraph (B) have been met, the Administrator shall immediately notify all registrants of such pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met.

(ii) Not later than 30 days after receipt of a notice provided under clause (i), a registrant may respond to such notice.

(iii) Not later than 60 days after the Administrator provides a notice under clause (i) concerning a pesticide, the Administrator shall determine whether a public interim administrative review of the pesticide shall be initiated.

(E) If the Administrator intends to initiate a public interim administrative review of a pesticide that is registered for agricultural uses, the Administrator shall notify the Secretary of Agriculture of the intention to initiate such review and the reasons therefor.

(F)(i) Any public interim administrative review proceeding shall be initiated and conducted in accordance with regulations published by the Administrator. Such regulations shall provide that a public interim administrative review shall include—

(I) a notice of initiation of the public interim administrative review and opportunity for public comment on such notice;

(II) a notice of a preliminary determination and opportunity for public comment on such notice; and

(III) a notice of a final determination,

except that such regulations may authorize the Administrator to combine or forgo any such notice.

(ii) Any proposed determination of the Administrator shall be submitted to the Scientific Advisory Panel established under section 25(d) at its next scheduled meeting for comment solely on relevant scientific issues. The public may submit comments to the Scientific Advisory Panel concerning such issues.

(iii)(I) The notice of the initiation of a public interim administrative review or the notice of a preliminary determination shall state the basis for such review or determination and include a request for any additional data needed and a bibliography of all scientific data and studies and

expert analyses concerning the risks or benefits of the pesticide that are under review.

(II) Information in the bibliography shall be made available to the public consistent with section 10. The Administrator shall determine, to the extent feasible, before the initiation of the public interim administrative review which data in the bibliography may be disclosed to the public under section 10(d)(1).

(II) If the Administrator receives additional data concerning such risks or benefits, the Administrator, within 30 days after receiving the additional data, shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

(iv)(I) Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments may be submitted on such review or determination. Any person who submits comments shall disclose to the Administrator all scientific data and studies and expert analyses in the possession of such person concerning the risks or benefits of the uses of the pesticide that are under review that were not included in the bibliography included in such notice.

(II) If such person receives additional scientific data or studies or expert analyses of such data or studies that were not included in such bibliography, the person shall disclose such scientific data, studies, and expert analysis to the Administrator within 30 days after receipt.

(v) Not later than 18 months after the initiation of a review, the Administrator shall decide which regulatory action (if any) to take regarding the pesticide that is the subject of the review and shall publish the decision.

(vi) The time limits specified in this subparagraph may not be extended, except in exceptional circumstances in which—

(I) additional data critical to a fair and accurate determination of risks posed by the pesticide subject to review are required;

(II) the extension is for a period limited to the time required to obtain such data on an expedited basis and in no event to exceed 1 year; and

(III) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for such data at such time.

(G) Any person may seek judicial review under section 16(a) of the failure of the Administrator to act within the time period prescribed under this paragraph.

(9) PREREGISTRATION ACCESS TO DATA.—

(A) If an application for—

(i) a registration of a pesticide containing a new active ingredient; or

(ii) a registration of a pesticide to authorize the initial food use of a pesticide active ingredient,

is submitted to the Administrator, the Administrator, before acting on such application, shall provide, in accordance with this paragraph, public access to health, safety, and environmental data that are submitted or cited in support of such application.

(B) To obtain access to the data referred to in subparagraph (A), a person shall send by certified mail—

(i) not later than 30 days after the publication under paragraph (4) of a notice of the application referred to in subparagraph (A); and

(ii) simultaneously to the Administrator and to the applicant for the registration of the pesticide,

a request for such access and the affirmation required by subparagraph (D).

(C)(i) Unless within 15 days after the receipt by the Administrator of a request for access to such data and of an affirmation complying with subparagraph (D) the applicant submits to the Administrator an objection to the request asserting that the affirmation is inaccurate and the reasons for the objection, the Administrator shall grant the request. If an objection to a request is submitted to the Administrator within such 15-day period, the Administrator shall determine whether to grant the request within 5 days after the receipt of the objection. If the Administrator determines to grant the request, access shall not be permitted until 5 days after the applicant making the objection has been notified that access has been granted.

(ii) If access to data is denied under clause (i), comments on the application for which such data were submitted or cited shall be filed within 60 days after the decision of the Administrator denying access.

(D)(i) Data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) containing the information prescribed by clause (ii).

(ii) The affirmation required under clause (i) shall—

(I) state that the person is not engaged in, and is neither employed by nor acting (directly or indirectly) on behalf of any other person or affiliate thereof engaged in, the production, sale, or distribution of a pesticide;

(II) identify any business, employer, or other person, if any, on whose behalf the person is requesting access to the data; and

(III) state that the person will not intentionally or recklessly violate this paragraph.

(iii) For purposes of clause (ii), an affiliate of a person is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the other person.

(iv) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

(E)(i) Data supporting an application may be made available under subparagraph (A) to a person only for the purpose of permitting the person to comment to the Administrator on such application. Such comments may reasonably quote data submitted to the Administrator. No person, including the Administrator, may make such comments public before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

(ii) Except as provided in clause (iii), a person who obtains data under subparagraph (A) (directly or indirectly) may not—

(I) publish, copy, or transfer the data to any other person to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world; or

(II) use the data for any purpose in any court or agency of the United States or any State or political subdivision thereof before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

(iii) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide for which such data were submitted.

(F)(i) Data made available under this paragraph may be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by this paragraph and may not be removed from such office.

(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of such record shall be sent to the data submitter on request.

(G) Once access to data respecting an application is granted, the data may be examined and notes may be taken for use in developing comments on the application. Such comments on the application shall be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator for an additional 30 days for good cause.

(d) CLASSIFICATION OF PESTICIDES.—

(1) CLASSIFICATION FOR GENERAL USE, RESTRICTED USE, OR BOTH.—

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use [, provided that if]. *If* the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation [on the initial classification] and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses [: *Provided, however;* That the]. *The* Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

* * * * * * *

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted [use:] *use.* If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. [Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.] *Any such regulation shall be reviewable in accordance with section 16(e).*

[(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

[(ii)]

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(f) MISCELLANEOUS.—

(1) EFFECT OF CHANGE OF LABELING OR FORMULATION.—**If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act.**

(2) REGISTRATION NOT A DEFENSE.—In no event shall registration of an article be construed as a defense for the commission on any offense under this Act [: *Provided,* That as]. *As* long as no cancellation proceedings are in effect registration of a

pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

* * * * * * *

[(g) REREGISTRATION OF PESTICIDES.—The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided,* That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process.]

(g) PRIORITY LIST AND DATA REQUIREMENTS FOR INERT INGREDIENTS.—

(1) ESTABLISHMENT OF LIST.—

(A) Subject to paragraph (4), the Administrator shall establish a priority list of inert ingredients consisting of—

(i) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8);

(ii) inert ingredients—

(I) for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment;

(II) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect; and

(III) that have significant use in pesticides or to which there is significant exposure from pesticides; and

(iii) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment and to which there is significant exposure from pesticides.

(B) In establishing the priority list, the Administrator shall take into account—

(i) the differences in concept, usage, and environmental risk between various classes of pesticides; and

(ii) data for evaluating such risk between agricultural and nonagricultural pesticides.

(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall publish the priority list required under paragraph (1). The Administrator shall publish revisions to such list at least annually.

(3) JUDICIAL REVIEW.—The priority list under paragraph (1), the inclusion or exclusion of an ingredient on or from the priority list, and any revision of the priority list shall not be subject to judicial review.

(4) NUMBER OF INGREDIENTS.—The priority list under paragraph (1) shall consist of not less than 50 inert ingredients unless the Administrator determines that there is not a sufficient number of inert ingredients meeting the requirements for

listing under paragraph (1) to reach such minimum number. Such list may not exceed 75 inert ingredients.

(5) Additional data.—

(A)(i) The Administrator shall determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list under paragraph (1).

(ii) The Administrator shall require submission of such data from each registrant of such pesticide under this Act or from manufacturers and processors of the inert ingredient under the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

(iii) Such data shall be submitted within a reasonable time but not later than 4 years after the date of the request. The Administrator may extend the period for the submission of data by not more than 2 years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the necessary data.

(B) Data requirements imposed under subparagraph (A) or a decision not to require data for an inert ingredient shall be subject to judicial review under section 16(b).

(6) Evaluation.—Within 1 year after the receipt of additional data under paragraph (5) for an inert ingredient, the Administrator shall evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment caused by pesticides containing such inert ingredient. Under exceptional circumstances, the Administrator may extend the period for evaluation by not more than 1 year.

(7) Construction.—This subsection shall not be construed to affect the authority of the Administration—

(A) to regulate under this Act impurities, contaminants, degradants, or other ingredients of pesticides that have not been deliberately added to the pesticides;

(B) to regulate under this Act any deliberately added inert ingredient that has not previously been used in a pesticide or a significant new use in a pesticide of a deliberately added inert ingredient;

(C) to require the submission of short-term, environmental fate, or residue studies for deliberately added inert ingredients; or

(D) to require the submission of revised formula statements under subsection (c)(2)(B).

(h) Neurotoxic and Behavioral Effects of Pesticides.—The administrator shall—

(1) conduct and support such research as the Administrator finds appropriate to develop methods for testing to more accurately detect neurotoxic and behavioral effects of pesticides and the ingredients of pesticides; and

(2) as such methods are developed, require that data from such testing be submitted by persons seeking to obtain or maintain pesticide registrations under this Act, to the extent appropriate and necessary.

[SEC. 3A.] ***SEC. 4.*** **REREGISTRATION OF REGISTERED PESTICIDES.**

(a) GENERAL RULE.—The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 3(c)(5) have been satisfied.

(b) SPECIAL AUTHORITIES OF ADMINISTRATOR.—

(1) GUIDELINES.—

(A) Not later than 1 year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator, by order, shall issue guidelines to be followed by registrants in accordance with subsection (f)(1) in—

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section.

(B) Guidelines issued under this paragraph shall not be subject to judicial review.

(2) MONITORING.—The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under this section.

(3) SUSPENSIONS AND PENALTIES.—

(A) The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if—

(i) the Administrator determines that progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under subsection (e)(3)(B) or (f)(1)(H) within the time period prescribed by subsection (e)(4)(B) or (f)(2)(B) or the registrant has not submitted such data to the Administrator within such time period;

(ii) the Administrator determines that tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under subsection (g)(1)(B);

(iii) the Administrator determines that progress is insufficient to ensure submission of the data referred to in clause (ii) within the time period prescribed by subsection (g)(2)(B) or the required data have not been submitted to the Administrator within such time period; or

(iv) a registrant fails to comply with clause (ii) or (iii) of section 3(c)(2)(B).

(B) A registrant who submits a certification under subsection (f)(1)(G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

(c) Reregistration Phases.—Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (d) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (e) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (f).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (g) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (h) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(d) Phase One.—

(1) Priority for reregistration.—For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) Reregistration lists.—For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, list pesticide active ingredients for which registration standards have been issued before such date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) JUDICIAL REVIEW.—The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) NOTICE TO REGISTRANTS.—On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (e) whether the registrants intend to seek or not to seek reregistration of such pesticides.

(e) PHASE TWO.—

(1) IN GENERAL.—The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

(2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) MISSING OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(iii) data identified under clause (i) that have not been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period pescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (f)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) TIME PERIODS.—

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(5) CANCELLATION AND REMOVAL.—

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such peticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Adminis-

trator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (d)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph (3)(A);

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A); or

(IV) the fee prescribed by subsection (j)(1) has not been paid with regard to the active ingredient,

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (d)(2) and a notice of intent to cancel the registations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

(A) during the comment period a person acquires the rights of the registrant in that registration;

(B) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(C) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by subsection (j)(1) has been paid.

(f) Phase Three.—

(1) Information about studies.—Each registrant of a pesti-ide that contains an active ingredient listed under subpara-raph (B), (C), or (D) of subsection (d)(2) who has submitted a otice under subsection (e)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under subsection (b)(1), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section but which

the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 6(g)(4) indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator prossesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing; and

(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

(2) Time periods.—

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a

reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(g) PHASE FOUR.—

(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUTSTANDING DATA REQUIREMENTS.—

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (e)(3) and (f)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this section, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (f)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

(2) Time periods.—

(A) The Administrator shall take the action required by paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 18 months after the date of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(h) Phase Five.—

(1) Data review.—The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (d)(2) and of all other available data found by the Administrator to be relevant.

(2) Reregistration and other actions.—

(A) Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (g), the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year.

(B) Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission. The Administrator shall require that data under this subparagarph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has

been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(i) COMPENSATION OF DATA SUBMITTER.—If data that are submitted by a registrant under subsection (e), (f), (g), or (h) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(j) FEES.—

(1) INITIAL FEE FOR FOOD OR FEED PESTICIDE ACTIVE INGREDIENTS.—The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $50,000 on submission of information under paragraphs (2) and (3) of subsection (e) for such ingredient.

(2) FINAL FEE FOR FOOD OR FEED PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $100,000—

(i) on submission of information for such ingredient under subsection (f)(1) if data are reformatted under subsection (f)(1)(C); or

(ii) on submission of data for such ingredient under subsection (f)(2)(B) if data are not reformatted under subsection (f)(1)(C).

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (d)(2)(A) and that is an active ingredient of any pesticide registered for a major use on food or feed shall collectively pay a fee of $100,000 at such time as the Administrator shall prescribe.

(3) FEES FOR OTHER PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is not an active ingredient of any

pesticide registered for a major use on food or feed shall collectively pay fees in amounts determined by the Administrator. Such fees may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant shall pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (d)(2)(A) and that is not an active ingredient of any pesticide that is registered for a major use on food or feed shall collectively pay a fee of not more than $100,000 and not less than $50,000 at such time as the Administrator shall prescribe.

(4) REDUCTION OR WAIVER OF FEES FOR MINOR USE AND OTHER PESTICIDES.—

(A) In the case of an active ingredient of a pesticide that is registered solely for an agricultural or nonagricultural minor use or in the case of a pesticide the value or volume of use of which is small, the Administrator, on application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3).

(B) In the case of an antimicrobal active ingredient for which the production level does not exceed 1,000,000 pounds per year, the Administrator, on application and in the sole discretion of the Administrator, may reduce or waive the fees prescribed by paragraph (3).

(C)(i) Notwithstanding any other provision of this subsection, in the case of a small business registrant of a pesticide, the registrant shall pay a fee for the reregistration of each active ingredient of the pesticide that does not exceed an amount determined in accordance with this subparagraph.

(ii) If during the 3-year period prior to reregistration the average annual gross revenue of the registrant from pesticides containing such active ingredient is—

(I) less than $5,000,000, the registrant shall pay 0.5 percent of such revenue;

(II) $5,000,000 or more but less than $10,000,000, the registrant shall pay 1 percent of such revenue; or

(III) $10,000,000 or more, the registrant shall pay 1.5 percent of such revenue, but not more than $150,000.

(iii) For the purpose of this subparagraph, a small business registrant is a corporation, partnership, or unincorporated business that—

(I) has 150 or fewer employees; and

(II) during the 3-year period prior to reregistration, had an average annual gross revenue from pesticides that did not exceed $40,000,000.

(5) OTHER FEES.—On payment of fees for the reregistration of a pesticide in accordance with paragraph (1), (2), (3), or (4), the Administrator may not levy any other fees for the reregistration with respect to that active ingredient.

(6) APPORTIONMENT.—

(A) If two or more registrants are required to pay any fee prescribed by paragraph (1), (2), or (3) with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the 3 calendar years preceding the date of payment of such fee, except that—

(i) small business registrants that produce the active ingredient shall pay fees in accordance with paragraph (4)(C); and

(ii) registrants who have not marketed the active ingredient during such 3 calendar years but who choose to reregister such active ingredient shall pay 15 percent of such fees.

(B) The Administrator, by order, may require registrants referred to in subparagraph (A) to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion fees under this subsection.

(C) If any such report is not submitted by a registrant after receiving notice of such report requirement, or if any fee prescribed by this subsection for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under this subsection, the Administrator, by order and without hearing, may cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the fee is imposed. The Administrator shall reapportion the fee among the remaining registrants and notify the registrants that the registrants are required to pay to the Administrator any unpaid balance of the fee within 30 days after receipt of such notice.

(k) EXEMPTION OF CERTAIN REGISTRANTS.—The requirements of subsections (e), (f), (g), and (j) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(l) REREGISTRATION FUND.—

(1) ESTABLISHMENT.—There shall be established in the Treasury of the United States a reregistration fund.

(2) SOURCE AND USE.—All fees collected by the Administrator under subsection (j) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out this section.

(3) UNUSED FUNDS.—Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(4) ACCOUNTING.—The Administrator shall—

(A) provide an annual accounting of the fees collected and disbursed from the fund; and

(B) take all steps necessary to ensure that expenditures of such funds are used only to carry out this section.

(m) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

SEC. 5. EXPERIMENTAL USE PERMITS.

(a) * * *

* * * * * * *

(f) STATE ISSUANCE OF PERMITS.—Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as he may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section **[**4**]** *11* relating the State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

(g) EXEMPTION FOR AGRICULTURAL RESEARCH AGENCIES.—Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require**[**: *Provided,* that such**]**. *Such* pesticide may be used only by such research agency or educational institution for purposes of experimentation.

SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

(a) CANCELLATION AFTER FIVE YEARS.—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect**[**: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment.**]**. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

[(1) PROCEDURE.—**]**

[(2) INFORMATION.—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.]

[(b) CANCELLATION AND CHANGE IN CLASSIFICATION.—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

[(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

[(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and make public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. It the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection (b) and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.]

(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.—

(1) NOTICE OF CANCELLATION OR CHANGE IN CLASSIFICATION.—

(A) If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent—

(i) to cancel its registration or to change its classification, together with the reasons (including the factual basis) for the action of the Administrator; or

(ii) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

(B) A notice issued under subparagraph (A) shall be sent to each registrant of the pesticide with respect to which the notice is issued and shall be made public.

(C) In determining whether to issue a notice under subparagraph (A), the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

(D)(i) Not later than 60 days before sending a notice to a registrant or making public such notice under subparagraph (B), whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of the proposed notice under subparagraph (A) and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture shall provide comments on such notice and analysis to the Administrator within 30 days after receiving the copy of such notice.

(ii)(I) If the Secretary of Agriculture provides such comments in writing 30 days after receiving the copy of such notice, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the comments of the Secretary.

(II) If the Secretary of Agriculture does not provide such comments in writing within 30 days after receiving the copy of such notice, the Administrator may notify the registrant and make public the notice at any time after such 30-day period.

(iii) The time requirements imposed by this subparagraph may be waived or modified to the extent agreed on by the Administrator and the Secretary of Agriculture.

(E) If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator may waive the requirements of notice of the Secretary of Agriculture prescribed by subparagraph (D) and submission to the Scientific Advisory Panel under section 25(d) and proceed in accordance with subsection (c).

(2) HEARING.—

(A) The action proposed in a notice issued under paragraph (1)(A) shall become final and effective at the end of 30 days after receipt by the registrant or publication of a notice issued under paragraph (1)(B), whichever occurs later, unless within that time—

(i) the registrant makes the necessary corrections, if possible; or

(ii) a request for a hearing is made by a person adversely affected by the notice.

(B) Whenever a request for a hearing is made, the request shall—

(i) identify with particularity the findings and conclusions of the decision of the Administrator that are disputed; and

(ii) include a complete statement of the reasons and factual basis that support the request for a hearing.

(C) Any party to the proceeding may identify findings and conclusions in dispute.

(D) If a hearing is held pursuant to such a request or the determination of the Administrator under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

(E) On receipt of a request for a hearing from a person without an economic interest in the pesticide with respect to which the hearing is requested, the Administrator shall convene such hearing if the request presents a substantial issue of fact, as determined by the Administrator, pertaining to whether such pesticide poses an unreasonable risk to man or the environment.

(3) FACTORS.—In taking any action under paragraph (1), the Administrator shall—

(A) consider restricting a use or uses of a pesticide as an alternative to cancellation and fully explain the reasons for such restriction; and

(B) consider the impact of such action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of such impact.

(4) LABEL CHANGES.—

(A)(i) The Administrator may—

(I) notify the registrant of a pesticide of a label change proposed by the Administrator that may be made by rulemaking under subparagraph (B); and

(II) provide that the registrant may submit comments to the Administrator on such proposed change during

the 30-day period beginning on the date of the receipt of such notice.

(ii) If a registrant who is notified by the Administrator of a proposed label change notifies the Administrator that the registrant does not object to such change, such change shall take effect as prescribed by the Administrator.

(iii) If a registrant who is notified by the Administrator of a proposed label change does not submit comments to the Administrator in such 30-day period, the Administrator shall send such registrant a second notice stating that, if such registrant does not submit any comments to the Administrator in the 30-day period beginning on the date the registrant receives the second notice, the registration of such registrant shall be canceled without a hearing or further notice. The registration of a registrant who does not submit comments on a second notice within such 30-day period shall be canceled without a hearing or further notice.

(iv) If in response to a notice under this subparagraph a registrant submits comments to the Administrator objecting to a proposed label change, the Administrator may proceed under subparagraph (B).

(B)(i) The Administrator may require changes to the label of a pesticide by informal rulemaking under this paragraph unless the changes—

(I) are equivalent to a cancellation of a use;

(II) render the pesticide unmarketable; or

(III) otherwise have a major economic impact on persons affected by such changes.

(ii) If the Administrator may not require changes to the label of a pesticide by informal rulemaking under this paragraph because of subclause (I), (II), or (III) or clause (i), the Administrator may only require such changes by a proceeding authorized by other provisions of this Act.

(C)(i) After the promulgation of a regulation under subparagraph (B), the Administrator shall—

(I) notify each registrant of the pesticide subject to the regulation of the label change required by the regulation; and

(II) provide a 30-day period for each registrant to apply to the Administrator for an amendment to the registration to comply with the regulation.

(ii) If a registrant does not apply for such an amendment within such period, the Administrator shall issue a notice of intent to cancel the registration of such registrant in accordance with paragraph (2). For purposes of paragraph (2), such notice shall be deemed to have been issued under paragraph (1).

(D) A registrant or user of a pesticide subject to a regulation issued under subparagraph (B) may request a hearing under subsection (d) on such regulation in accordance with paragraph (2). The scope of the hearing shall be limited to—

(i) whether the pesticide complies with the regulation;

(ii) whether the regulation by its terms is applicable to such pesticide; and

(iii) whether, because of significant information that was not (and could not reasonably have been) presented in the proceeding wherein the regulation was promulgated, it would be unreasonable to require such pesticide to comply with the regulation.

(E)(i) Except as provided in clause (ii), in an action under 16(e) for review of a regulation issued under subparagraph (B), the court, on request, shall postpone the effective date of the regulation until completion of the review action if the petitioner shows—

(I) a likelihood of success on the merits in such action; and

(II) that the implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner.

(ii) A court in a review action under section 16(e) shall not postpone the effective date of a regulation issued under subparagraph (B) if the Administrator shows that failure to implement the regulation before completion of the action would cause a risk of substantial harm to health or the environment.

(c) SUSPENSION.—

(1) ORDER.—If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide. Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard." The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the **[**Agency**]** *Administrator* on the question of whether an imminent hazard exists.

(2) EXPEDITE HEARING.—If no request for a hearing is submitted to the **[**Agency**]** *Administrator* within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the **[**Agency**]** *Administrator* agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended find-

ings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order.—Whenever the Administrator determines that an emergency exists that does not permit him to hold a hearing before suspending, he may issue a suspension order in advance of notification to the registrant. In that case, paragraph (2) shall apply except that [(i)] *(A)* the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and [(ii)] *(B)* no party other than the registrant and the [Agency] *Administrator* shall participate except that any person adversely affected may file briefs within the time allotted by the [Agency's] *Administrator's* rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 16(b).

(4) Judicial review.—A final order on the question of suspension following a hearing shall be reviewable in accordance with Section 16 of this Act, notiwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceeding under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public Hearings [and Scientific Review].—In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedures in making any order for the protection of the witness or the content of documents produced and shall order the payments of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. [Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective with competant scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this Act.] As soon as practicable after completion of the hearing [(including the report of the Academy)] but not later than [90 days thereafter] *18 months afer issuance of the notice that gave rise to the hearing,* the Administrator shall evaluate the data and reports before him and issue an order either revoking his notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. *The time period prescribed by the preceding sentence may be extended by the Administrator under extraordinary circumstances for not more than 1 year.* Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) CONDITIONAL REGISTRATION.—

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 3(c)(7) of this Act if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met [: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment].

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section [: *Provided,* That the]. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or con-

ditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determiniation made within seventy-five days after receipt of a request for such hearing.

(f) HEARING PROCEDURES AFTER PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

(1) GENERAL RULE.—Except as provided in paragraphs (2) and (3), subsection (d) shall govern any hearing under such subsection—

(A) that results from the final determination of the Administrator in a public interim administrative review proceeding under section 3(c)(8) that is initiated after January 1, 1987;

(B) that includes an opportunity for comment on a notice of preliminary determination issued in connection with such review; and

(C) for which the time between the first public notice for such review under section 3(c)(8)(F) and the close of the last comment period provided for such review is not less than 180 days.

(2) REQUEST FOR HEARING.—Any person who is adversely affected by a decision of the Administrator respecting a pesticide (including a person without an economic interest in such pesticide) following a public interim administrative review described by paragraph (1) may request, or intervene in, a hearing in the manner provided by subsection (b)(2)(B) within 30 days after such decision. A person may request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with section 3(c)(8)(F).

(3) PROCEDURES.—

(A) At the request of a party, an administrative law judge conducting a hearing may receive into evidence portions of a public interim administrative review record and other evidence, if the party demonstrates that such portions of the record and other evidence are relevant and material to the disputed issues and are not unduly repetitious, and if a competent witness is made available to be cross-examined on all matters relating to such evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the public interim administrative review proceeding by the exercies of due diligence by the offering party shall not be admissible.

(B) The right of other parties to confront and cross-examine witnesses with respect to such evidence shall be preserved with respect to material issues of adjudicative fact, so long as such cross-examination is not unduly repetitious.

(C)(i) Not later than 120 days after an administrative law judge is appointed, prehearing matters shall be completed and the hearing shall commence.

(ii) The administrative law judge may establish a schedule for prehearing matters, including discovery and motions, and shall ensure that the hearing schedule is met. The administrative law judge shall issue such orders as are appropriate for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision.

(iii) Discovery shall be permitted after the expiration of 120 days after the appointment of the administrative law judge on a determination by the administrative law judge that—

(I) such discovery shall not in any way unreasonably delay the proceeding;

(II) the information to be obtained is not otherwise obtainable; and

(III) such information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

(D) Any challenge to—

(i) the authority to issue; or

(ii) the procedural correctness of the issuance of,

any notice to intent to cancel or change classification or to any request for a hearing or motion to intervene shall be filed with the administrative law judge not later than 30 days before the commencement of the evidentiary phase of the hearing.

(E) Not later than 30 days before the hearing commences, each party shall make available to the other parties the names of the expert and other witnesses the party expects to call, together with a brief narrative summary of their expected testimony and a list of all documents and exhibits that the party expects to introduce into evidence. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended on motion by a party.

(F) If new studies become available that were not available during the public interim administrative review, the administrative, law judge, on request of any party and when in the judgment of the administrative law judge it is necessary, may submit such studies to the Scientific Advisory Panel established under section 25(d) for supplemental comment on an expedited basis under such time limits as may be established by the administrative law judge.

(G) The administrative law judge shall schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after the commencement of the hearing, except that the schedule shall not prejudice the right of a party to present evidence. The person who requested a hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue.

(H) A hearing conducted in accordance with this subsection shall be completed and the Administrator shall make

a final decision within 300 days after the issuance of the notice that gave rise to the hearing. The time limit imposed by this subparagraph may not be extended, except in exceptional circumstances in which such extension is essential for a fair and accurate determination of pivotal facts central to the proceeding. In no event may such time limit be extended more than 180 days. Any other time limit imposed by this paragraph may be extended for good cause.

(I) Failure to complete a hearing and make a final decision within the time period prescribed by subparagraph (H) shall be grounds for a civil action in a district court of the United States seeking an order to establish a schedule requiring the prompt completion of the hearing, but shall not be grounds for termination of the hearing or for making a final decision respecting the pesticide that is the subject of the hearing.

(g) GENERAL PROVISIONS.—

(1) VOLUNTARY CANCELLATION.—A registrant at any time may request that any of its pesticide registrations be cancelled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request.

(2) PUBLICATION OF NOTICE.—A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act, a notice issued under subsection (d)(4) or (e)(5)(A) of section 4, or a notice issued under the third sentence of subsection (b)(4)(A) shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) EXISTING STOCKS.—The Administrator may permit the continued use, distribution, or sale, or any combination thereof, of existing stocks of a pesticide whose registration is canceled under this Act to such extent, under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.

(4) ADDITIONAL INFORMATION.—If at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator. For purposes of this paragraph, the term 'information' includes factual information and expert opinion regarding risks or benefits.

(h) SUSPENSION AND CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

(1) NOTICE.—

(A) The Administrator shall immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if—

(i) before the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator has previously determined in the Industrial Biotest validation process conducted by the Administrator that data submitted by the registrant of the pesticide to the Administrator in support of such registration were invalid;

(ii) the data referred to in clause (i)—

(I) have not been replaced as of the effective date of such Act; or

(II) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988; and

(iii) such data are material to the registration.

(B) The Administrator may issue an order of suspension and a notice of intent to cancel the registration of a pesticide by a registrant who cited data described in subparagraph (A) in support of the registration of the pesticide.

(2) INVALID DATA.—

(A) If, after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator determines that invalid data are submitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

(i) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

(ii) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

(B) If, after the effective date of such Act, the Administrator determines that invalid data are cited by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

(i) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

(ii) issue a notice of intent on cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue notices of intent to suspend and cancel such registration.

(4) HEARING.—

(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on the date of receipt by the registrant of a notice issued under this subsection unless during such period a request for a hearing is made by a person adversely affected.

(B) A hearing under this paragraph shall be conducted in accordance with the procedures prescribed by subsection (c) or (d), as appropriate.

(C) In the case of a hearing held with respect to action proposed to be taken under paragraph (1), the only matters for resolution shall be whether—

(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data previously determined by the Administrator to be invalid—

(I) have not been replaced as of the effective date of the Federal Insecticide, Fungicide, or Rodenticide Act Amendments of 1986; or

(II) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988; and

(ii) the data are material to the registration.

(D) In the case of a hearing held with respect to action proposed to be taken under paragraph (2), the only matters for resolution shall be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment.

(E) In the case of a hearing held with respect to action proposed to be taken under paragraph (3), the only matters for resolution shall be whether a registrant willfully submitted material data known to be false.

(F) A decision after completion of a hearing conducted under this paragraph shall be final.

(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after the receipt of a request for such hearing.

[(f)**]***(i)* JUDICIAL REVIEW.—Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 16.

SEC. 7. REGISTRATION OF ESTABLISHMENTS.

(a) * * *

* * * * * * *

(c) INFORMATION REQUIRED.—

(1) Any producer operating an establishment registered under this section shall **[**inform the Administrator**]**, *in accordance with regulations promulgated by the Administrator, submit to the Administrator a report* within 30 days after is is registered **[**of the**]** *describing* types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which he is currently producing;
(B) which he has produced during the past year; and
(C) which he has sold or distributed the past year.

The [information] *report* required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop order pursuant to section 13, inform him of the name and address of any recipient of any pesticide produced in any registered establishment which he operates.

(d) Confidential Records and Information.—Any information submitted to the Administrator pursuant to subsection (c) other than the names *and production locations* of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10.

(e) Public Right to Know.—

(1) Fact sheets.—Any producer operating an establishment in any State shall prepare or obtain a fact sheet complying with this subsection for each active ingredient manufactured or used at the establishment. The producer shall maintain copies of the fact sheet at the establishment and shall furnish a copy to any person on request.

(2) Contents.—

(A) Each fact sheet for an ingredient required under paragraph (1) shall—

(i) contain the chemical name, each common name, and any trade name of the ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient; and

(ii) be revised as often as is necessary to reflect current information about the ingredient.

(B) The Administrator may require a fact sheet to be amended to provide accurate and clear information to the public.

(3) Reports.—Each producer to whom this subsection applies shall furnish to the Administrator annually, in accordance with regulations published by the Administrator, a report that includes—

(A) for each establishment operated by the producer in any State, the name of each ingredient for which a fact sheet is required that is manufactured or used at that establishment;

(B) for each ingredient for which a fact sheet is required, the location of each establishment where such ingredient is manufactured or used by the producer; and

(C) a current copy of each required fact sheet.

(4) Public availability.—The fact sheets required by paragraph (1) and the annual reports required by paragraph (3) shall be available to the public.

(f) Information Requests.—Consistent with section 3507(a)(1) of title 44, United States Code, the Administrator shall catalog and re-

trieve data in such a manner as to eliminate or reduce burdensome requests to registrants for submission of information, particularly requests that require the submission of duplicate confidential data.

[SEC. 8. BOOKS AND RECORDS.

[(a) REQUIREMENTS.—The Administrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

[(b) INSPECTION.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable time to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.]

SEC. 8. RECORDS.

(a) AUTHORITY TO REQUIRE RECORDS.—

(1) IN GENERAL.—The Administrator, by regulation, may require any producer or exporter of pesticides, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, or commercial applicator, or any person who distributes or sells any pesticide—

(A) to prepare, and to maintain for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act;

(B) to furnish to the Administrator reports stating the location where the records are maintained; and

(C) to furnish a copy of any such record to the Administrator on written request.

(2) RETAIL DISTRIBUTION OR SALE.—Except as provided in subsections (c), (d), and (e), the Administrator may not require any person who distributes or sells at retail a registered pesticide that is not subject to a restricted use classification under section 3 to prepare, maintain, or furnish any record under this subsection with respect to such pesticide.

(b) LIMITATIONS.—The Administrator may not, under the authority of subsection (a), require any person to maintain records of—

(1) financial data, sales, data, or pricing data;

(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure; or

(3) research or test data (other than data relating to a registered pesticide, data relating to any pesticide for which an application for registration or for an experimental use permit has been filed, or data relating to testing at a pesticide testing facility).

(c) RECORDS OF APPLICATORS.—

(1) COMMERCIAL APPLICATORS.—The Administrator shall require each commercial applicator to maintain records of each pesticide application, including the identity and quantity of pesticide applied and the date and location of such application, for a period of 2 years after each such application.

(2) PRIVATE APPLICATORS.—No regulations issued by the Administrator to carry out this Act may require any private applicator to maintain any records or file any reports or other documents.

(d) RECORDS OF PESTICIDE DEALERS.—

(1) IN GENERAL.—The Administrator, by regulation, shall require each pesticide dealer to maintain a record of each sale or distribution of—

(A) a pesticide classified for restricted use; and

(B) any other pesticide designated for purposes of this subsection by the Administrator by regulation because the pesticide may cause significant adverse effects on health or the environment.

(2) CONTENTS.—Such records shall include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold.

(3) DURATION.—A pesticide dealer shall maintain the records required under this subsection for 3 years after the date of the distribution or sale.

(e) ACCESS.—

(1) EMPLOYEES, CUSTOMERS, AND COMPLAINANTS.—

(A) A pesticide dealer or commercial applicator shall afford to an employee or former employee of such dealer or applicator access to records required to be kept under sub-

sections (c) and (d) that directly relate to the employment duties of the employee.

(B) A pesticle dealer or commercial applicator shall afford to a customer of such dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by such an applicator at the request of the customer or under a contract with a customer.

(C) Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, shall make available reports of the findings of such investigation or action to the complainant. On the request of a complainant, such agency shall provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action.

(D) The records for which access is provided under subparagraph (A), (B), or (C) shall be accessible within 30 days after a request made under such subparagraph, except that if necessary to protect the public health or in a medical emergency, such records shall be provided as soon as possible, but no later than 24 hours, after the request is made.

(2) STATE AGENCIES.—A copy of any record to be required to be maintained under subsection (c) or (d) shall be submitted to a State agency that has primary enforcement authority under section 26 on request by such State agency to the commercial applicator or dealer required to maintain such records.

(f) INFORMATION FOR EMPLOYEES.—An employer who uses or supervises the use of a pesticide shall—

(1) know or have access to the brand name and common or chemical name of each ingredient listed on the labeling of the pesticide, and to the safety, first aid, and antidote information listed on the labeling of the pesticide; and

(2) be responsible for promptly making such information available, on request, to any employee exposed to the pesticide and to treating medical personnel.

SEC. 9 INSPECTION OF ESTABLISHMENTS, ETC.

[(a) IN GENERAL.—For purposes of enforcing the provisions of this Act, officers or employees duly designated by the Administrator are authorized to enter at reasonable times, any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices.

[Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.]

(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—An officer or employee of the United States or of any State, duly designated by the Administrator, is authorized at reasonable times, as provided by this seciton—

(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place or of any packaging or labeling of any such pesticide, active ingredient, or device;

(2) to enter any place where there are located any records required under this Act or any place reported under section 8(a) as a location where such records are maintained, to inspect and obtain copies of such records;

(3) to enter any pesticide testing facility—

(A) to inspect the facility and the testing being conducted at the facility; and

(B) to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility; and

(4) to enter any place where such officer or employee has reason to believe that this Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, to inspect such place to obtain evidence of such violation.

[(b) WARRANTS.—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

[(1) entry for the purpose of this seciton;

[(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or divice found in the establishment which is adulterated, misbranched, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to delivery, movement, or holding of the pesticide or device; and

[(3) the seizure of any pesticide or device which is in violation of this Act.]

(b) WARRANTS.—An officer or employee of the United States or of any State, duly designated by the Administrator, is empowered to obtain and execute warrants authorizing—

(1) entry, inspection, and obtaining of evidence for the purposes of this section;

(2) inspection and copying of all records required under this Act; and

(3) seizure of any pesticide or device that is in violation of this Act.

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(d) PROCEDURE.—

(1) CREDENTIALS AND STATEMENTS.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the entry or inspection and whether a violation of this Act is suspected.

(2) PROMPTNESS.—Each entry or inspection shall be commenced and completed with reasonable promptness.

(3) SAMPLES.—If the person conducting the entry or inspection obtains a sample of a pesticide or device, before leaving the premises such person shall give to the person in charge of the premises a receipt describing the sample and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analysis shall be furnished on request to the person in charge of the premises.

(e) COORDINATION.—The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws for the purpose of avoiding duplication of inspections.

(f) CRIMINAL VIOLATIONS.—An officer or employee of the United States or of any State, duly designated by the Attorney General, may obtain and execute a warrant in accordance with rule 41 of the Federal Rules of Criminal Procedure if a court or magistrate determines under such rule that there is probable cause to believe that—

(1) a criminal violation of this Act has occurred or is occurring on the property to be entered or searched; or

(2) evidence of a criminal violation of this Act will be found on such property.

SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) * * *

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(d) LIMITATIONS.—

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public**[**: *Provided,* That the**]**. *The* use of such data for any registration purpose shall be governed by section 3 of this Act**[**: *Provided further,* That this**]**. *This* paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identify or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

* * * * * * *

(3) **[**If**]** *Except with respect to disclosure of information on inert ingredients in ingredient statements in accordance with section 2(n), if* the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice**[**: *Provided,* That where**]**. *Where* the Administrator finds that disclosure of information described in clause (A), (B) or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

* * * * * * *

(h) DATA DISCLOSURE TO STATES.—

(1) IN GENERAL.—The Administrator may disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section.

(2) ACTION FOR JUST COMPENSATION.—For the purpose of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code—

(A) the disclosure or use of data or information provided by the Administrator under paragraph (1) to a State in a manner inconsistent with this section or section 3 shall be considered a taking of property; and

(B) the act of a State with respect to such data or information shall be considered an act of the United States.

(3) REQUIRED DISCLOSURE.—The Administrator shall disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that—

(A) the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section; and

(B) the law of the State allows the submitter of the data or information to recover just compensation in a civil action against the State for losses resulting from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or this section.

[SEC. 11. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

[(a) IN GENERAL.—No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

[(b) SEPARATE STANDARDS.—When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.]

[SEC. 4.] *SEC. 11.* USE OF RESTRICTION USE PESTICIDES; CERTIFIED APPLICATORS.

(a) CERTIFICATION PROCEDURES.—

(1) FEDERAL CERTIFICATION.—In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides[: *Provided,* That such]. *Such* program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the com-

mercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification[: *Provided, however,* That the]. *The* certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may *by regulation* require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by him.

* * * * * * *

(d) USE BY COMMERCIAL APPLICATORS.—

(1) IN GENERAL.—It shall be a violation of this Act for any person to use any pesticide as a commercial applicator unless such person is—

(A) a certified commercial applicator; or

(B) a registered commercial applicator under the direct supervision of a certified commercial applicator.

(2) CERTIFIED COMMERCIAL APPLICATORS.—To be considered to be a certified commercial applicator, a person, at a minimum, shall—

(A) have met the standards prescribed under subsection (a) and have received training—

(i) prescribed by the State agency, including training in the material referred to in subsection (g);

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(iii) that satisfies the minimum standards for training programs prescribed under subsection (h);

(B) have had field, institutional, or industrial experience in pesticide use and application;

(C) have passed an examination prescribed by such State agency; and

(D) possess a valid commercial applicator certification issued by such State agency.

(3) REGISTERED COMMERCIAL APPLICATORS.—

(A) To be considered to be a registered commercial applicator, a person, at a minimum, shall—

(i) have received training—

(I) prescribed by the State agency, including training in the material referred to in subsection (g); and

(II) conducted by a trainer who has met requirements prescribed under subsection (h); and

(ii) possess a valid registration issued by such State agency.

(B) A person may obtain a registration by providing to the State agency a report, signed and dated by the trainer and by the person who received the training, stating that the prescribed minimum training has been provided and received.

(e) USE BY PRIVATE APPLICATORS.—

***(B) possess a valid private applicator certification issued** by such State agency.*

(1) IN GENERAL.—A restricted use pesticide shall be considered to have been applied by, or under the direct supervision of, a certified private applicator only if the pesticide is applied by a person who is either—

(A) a certified private applicator; or

(B) a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator.

(2) CERTIFIED PRIVATE APPLICATORS.—To be considered to be a certified private applicator, a person, at a minimum, shall—

(A) have met the standards prescribed under subsection (a) and have received training—

(i) prescribed by the State agency, including training in the material described in subsection (g);

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(iii) that satisfies the minimum standards for training prescribed under subsection (h); and

(3) SUPERVISED PRIVATE APPLICATORS.—

(A) To be considered to be a supervised private applicator, a person, at a minimum, shall have received basic instruction—

(i) prescribed by the State agency or based on material prescribed by such State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling; and

(ii) given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the requirements prescribed under subsection (h).

(B) The State agency may require the employer of a supervised private applicator to confirm that the basic instruction described in subparagraph (A)(i) has been received.

(f) Recertification and Reregistration.—

(1) In general.—Each certified applicator and each registered commercial applicator within a State shall undergo refresher training and be recertified or reregistered within a period established by the State agency of such State of not more than 5 years.

(2) Training material.—The refresher training shall be prescribed by the State agency and shall include training in the materials referred to in subsection (g) and in the relevant requirements of other subsections of this section and sections 3(d), 12, and 14.

(3) Recertification.—To be recertified, an applicator, at a minimum, shall meet—

(A) the requirements of subparagraphs (A), (B), and (D) of subsection (d)(2); or

(B) the requirements of paragraphs (1) and (2) of subsection (e).

(4) Reregistration.—To be reregistered, a commercial applicator, at a minimum, shall meet the requirements of subsection (d)(3).

(g) Training Material.—

(1) Development.—The Administrator, in consultation with the Secretary of Agriculture, shall develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling.

(2) Revisions.—Within 12 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator, in consultation with the Secretary of Agriculture, shall revise and make current such material and thereafter shall update such material as needed.

(h) Minimum Standards for Trainers and Training Programs.—

(1) Training of commercial applicators.—

(A) The Administrator shall establish within 1 year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986—

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (d); and

(ii) minimum standards for the training programs referred to in subsection (d).

(B) Training programs prescribed by any State under subsection (d) shall comply with the mininum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards.

If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards. If on expiration of such 90-day period, the training program of the State does not meet such standards, the Administrator shall prescribe such training programs referred to in subsection (d) for use in such State.

(2) TRAINING OF PRIVATE APPLICATORS.—

(A) The Administrator shall establish within 2 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986—

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (e); and

(ii) minimum standards for the training programs referred to in subsection (e).

(B) Training programs prescribed by any State under subsection (e) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period the training program of a State fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards. If on expiration of such 90-day period the training program of the State does not meet such standards, the Administrator shall prescribe the training programs referred to in subsection (e) for use in such State.

(i) PRIVATELY ADMINISTERED TRAINING PROGRAMS.—A State agency may approve any privately administered training program that the Administrator determines meets the more stringent of—

(1) requirements established under this section; or

(2) requirements established by the State agency.

(j) ENFORCEMENT OFFICER TRAINING.—Federal and State field personnel responsible for on-site observations and inspections of pesticide use shall have training that, at a minimum, includes training covering materials specified in subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

(k) SEPARATE STANDARDS.—In establishing standards under this section applicable to applicators, the Administrator shall establish separate standards for commercial applicators and private applicators.

(l) DEFINITION OF STATE AGENCY.—For purposes of this section, the term 'State agency' means the agency of a State that is designated under subsection (a)(2)(A) if the State has primary enforcement responsibility for pesticide use violations, as provided for by section 26. In the case of a State that does not have such primary enforcement responsibility or that does not have an agency designated

under subsection (a)(2)(A), a reference to a State agency shall be considered a reference to the Administrator.

SEC. 12. UNLAWFUL ACTS.

(a) In General.—

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to [distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—] *distribute or sell to any person—*

[(A) any pesticide which is not registered under section 3, except as provided by section 6(a)(1);]

(A) any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;

* * * * * * *

(2) It shall be unlawful for any person—

(A) * * *

[(B) to refuse to keep any records required pursuant to section 8, or to refuse to allow the inspection of any records or establishment pursuant to section 8 or 9, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 9;]

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under this Act;

(ii) submit any reports required by or under this Act; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this Act;

* * * * * * *

(F) *to distribute or sell, or* to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder [: *Provided,* That it]. *It* shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

* * * * * * *

[(J) to violate any suspension order issued under section 6;]

(J) to violate any suspension order issued under section 3(c)(2)(B), 4, or 6;

[(K) to violate any cancellation or registration of a pesticide under section 6, except as provided by section 6(a)(1);]

(K) to violate any cancellation order issued under this Act;

* * * * * * *

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to [section 8,] *this Act,* any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

* * * * * * *

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act; [or]

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test [.];

(Q) to obtain or use records acquired under section 8(e) in furtherance of a commercial purpose;

(R) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

(S) to submit to the Administrator data known to be false in support of a registration;

(T) to violate any regulation issued under section 3(a), 19(a), 25(c)(3), or 25 (f); or

(U) to violate an order issued under section 31(e)(2).

* * * * * * *

(c) Acts of Officers, Agents, Etc.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person shall be deemed to be the act, omission, or failure of such person as well as that of the person employed.

SEC. 13. STOP SALE, USE, REMOVAL, AND SEIZURE.

(a) * * *

(b) Seizure.—Any pesticide or device that is being transported, or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 3;

(C) its labeling fails to bear the information required by this Act;

(D) it is not colored or discolored and such coloring or discoloring is required under this Act; or

(E) any of the claims made for it or any of the directions for its use differ in substance for the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold: ⟦*Provided,* That upon⟧. *On* payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

* * * * * * *

SEC. 14. PENALTIES.

(a) CIVIL PENALTIES.—

⟦(1) IN GENERAL.—Any registrant, commerical applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.⟧

(1) IN GENERAL.—

(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If a registrant, applicant for a registration, producer, or pesticide testing facility violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $50,000 for such subsequent violation.

(B) Any—

(i) commercial applicator of restricted use pesticides; or

(ii) any other person not described in subparagraph (A) who distributes or sells pesticides or devices,

that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $20,000 for such subsequent violation.

[(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense: *Provided,* That any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or use dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $500 for the first offense nor more than $1,000 for each subsequent offense.]

(2) PRIVATE APPLICATOR.—Any private applicator who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, and any other person not included in paragraph (1) that violates any provision of this Act, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $2,000 for such subsequent violation. The Administrator may waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused significant harm to health or the environment.

(3) HEARING.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged. *If the person neither resides nor has a principal place of business in the United States, the Administrator may designate a site for the hearing in the United States that is reasonably convenient for the parties.*

(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, *the economic benefit (if any) resulting from the violation,* and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environ-

ment, the Administrator may issue a warning in lieu of assessing a penalty.

* * * * * * *

(6) SUBPOENAS.—The Administrator, in connection with administrative proceedings under this subsection, may issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and may request the Attorney General to bring an action to enforce any subpoena issued under this paragraph. The district courts of the United States shall have jurisdiction to enforce such subpoenas and impose sanctions.

(b) CRIMINAL PENALTIES.—

[(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both.**]**

(1) IN GENERAL.—

(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that knowingly violates any provision of this Act shall be fined not more than $50,000 or imprisoned for not more than 2 years or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, that knowingly violates any provision of this Act shall be fined not more than $25,000 or imprisoned for not more than 2 years, or both.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than **[**$1,000,**]** *$2,000,* or imprisoned for not more than **[**30**]** *60 days,* or both.

[(3) DISCLOSURE OF INFORMATION.—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than $10,000, or imprisoned for not more than three years or both.**]**

(3) DISCLOSURE OF INFORMATION.—

(A) Any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 shall be fined not more than $25,000 or imprisoned for not more than 3 years, or both.

(B) Any person, including any officer, contractor, or employee of the United States or a State, who—

(i) is granted access to data under section 3(c)(9); and

(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

(I) knowingly violates such section; or

(II) knowingly allows data to be made available in violation of such section,

shall be fined not more than $100,000 or imprisoned for not more than 3 years, or both.

[(4) ACTS OF OFFICERS AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.]

SEC. 15. INDEMNITIES.

(a) REQUIREMENT.—If—

(1) the Administrator notifies a registrant that he has suspended the registration of a pesticide because such action is necessary to prevent an imminent hazard;

(2) the registration of the pesticide is canceled as a result of a final determination that the use of such pesticide will create an imminent hazard; and

(3) any person who owned any quantity of such pesticide immediately before the notice to the registrant under paragraph (1) suffered losses by reason of suspension or cancellation of the registration,

the Administrator shall make an indemnity payment to such person, unless the Administrator finds that such person [(i)] had knowledge of facts which, in themselves, would have shown that such pesticide did not meet the requirements of section 3(c)(5) for registration, and [(ii)] continued thereafter to produce such pesticide without giving timely notice of such facts to the Administrator.

* * * * * * *

(c) INDEMNIFICATION.—

(1) REPORTS.—If the Administrator takes an action that under subsection (a) requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on appropriations of the House of Representatives and the Senate—

(A) the action taken that requires the payment of indemnification;

(B) the reasons for taking such action;

(C) the estimated cost of the payment; and

(D) a request for the appropriation of funds for such payment.

(2) APPROPRIATION REQUIRED.—The Administrator may not make such payment unless a specific line item appropriation of funds has been made in advance for such payment.

SEC. 16. ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW.

[(a) DISTRICT COURT REVIEW.—Except as is otherwise provided in this Act, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts.]

(a) District Court Review.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

* * * * * * *

(e) Review of Regulations.—

(1) In General.—

(A) Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986 shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the regulation by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any petition under this paragraph for review of a regulation shall be filed within 120 days after the date of promulgation of the regulation as designated by the Administrator in the Federal Register.

(B) Any refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review or a refusal to modify or rescind a regulation shall be filed within 120 days after such refusal.

(C) The scope of review under subparagraph (A) or (B) shall be as specified in section 706 of title 5, United States Code. The commencment of a proceeding under subparagraph (A) or (B), unless specifically ordered by the court to the contrary, shall not operate as a stay of the regulation.

(2) Judicial Review.—A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall not be subject to judicial review—

(A) in any suspension, cancellation, or denial proceeding under this Act or in any appeal therefrom; or

(B) in any proceeding under section 13 or 14(a), or subsection (c), or in any appeal therefrom except on request of a person who, as an agricultural producer, is adversely affected by such action.

(3) Stays.—If a person who is a party to a proceeding described in subparagraph (A) or (B) of paragraph (2) that is based on a regulation issued under this Act petitions the Administrator to modify or rescind such regulation, the application of such regulation in the proceeding shall be stayed until the Administrator issues a final decision on the petition.

(4) Definition of Agricultural Producer.—As used in this subsection, the term "agricultural producer" means a nongovernmental producer of agricultural commodities who—

(A) uses or supervises the use of any pesticide for the production of such commodities on property owned or rented by the producer or the employer of the producer; or

(B) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the land of the producer.

SEC. 17. IMPORTS AND EXPORTS.

[(a) Pesticides and Devices Intended for Export.—Notwithstanding any other provision this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

[(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C)(i) and (iii), and (D), 7, and 8 of this Act; and

[(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.]

(a) Pesticides and Devices Intended for Export.—

(1) Violations.—Notwithstanding any other provision of this Act, no pesticide or device, or active ingredient used in producing a pesticide, intended solely for export to any foreign country shall be considered in violation of this Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to section 2(p), subparagraphs (A), (C), (D), (E), (G), (H), and (I) of section 2(q)(1), subparagraphs (A), (B), (C)(i), (C)(iii), and (D) of section 2(q)(2), sections 7 and 8 and paragraphs (2), (3), and (4) of this subsection.

(2) Export of restricted use or unregistered pesticides.—

(A) This paragraph applies to a pesticide, device, or active ingredient—

(i) for which a restricted use classification has become effective under section 3;

(ii) for which a cancellation or suspension has become effective under section 6;

(iii) the registration of which has been voluntarily withdrawn by the registrant, if such withdrawal is associated with concern over potential adverse public health or environmental effects; or

(iv) that is not registered under section 3 for any use.

(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any foreign country by any person unless—

(i) at least 30 days before the first shipment each year of such pesticide, device, or active ingredient to such country, the Administrator has notified, under paragraph (3), the appropriate government regulatory office in the importing country; and

(ii) prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act.

(C) A copy of the statement required under subparagraph (B)(ii) shall be transmitted to an appropriate official of the government of the importing country.

(D) Documents referred to in subparagraph (B) shall be made available to the public, on request.

(3) Notification specifications.—The notification required under paragraph (2) shall be made in an appropriate language and shall contain—

(A) the name of the pesticide and the common and chemical names of each active ingredient;

(B) the name and address of the person exporting the pesticide, device, or active ingredient;

(C) the name and address of the person importing the pesticide, device, or active ingredient;

(D) the name and address of the appropriate government regulatory office in the importing country;

(E) a statement of the reasons why the registration of the pesticide was canceled, suspended, voluntarily withdrawn, or the pesticide, is not registered in the United States, or is classified for restricted use, and the list of restrictions; and

(F) the name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

(4) Labels.—

(A) The label of a pesticide intended for export from the United States shall be written in an appropriate language.

(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.

(5) Records.—The Administrator, by regulation, may require any person subject to this subsection to prepare, maintain, and submit such records as may be necessary to carry out this subsection.

[(b) Cancellation Notices Furnished to Foreign Governments.—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.]

(b) Notices of Regulatory Action Furnished to Foreign Governments.—

(1) Issuance.—The Administrator shall promptly transmit through the Secretary of State a notice, at such time and annually thereafter, to the appropriate governmental regulatory offices of other countries and to appropriate international agencies whenever—

(A) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective; or

(B) a pesticide is classified for restricted use.

(2) Contents.—A notice under paragraph (1) shall include—

(A) the reasons for the regulatory action taken;

(B) in the case of a canceled or suspended registration of a pesticide, information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide; and

(C) the name and address of the office of the United States Environmental Protection Agency that, on request, can provide additional information on the pesticide.

(c) Importation of Pesticides and Devices.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe [: *Provided*, That the]. *The* Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond [: *And provided further*, That all]. *All* charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 18. EXEMPTION OF FEDERAL *AND STATE* AGENCIES

The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

SEC. 19. DISPOSAL AND TRANSPORTATIONS.

(a) PROCEDURES.—Administrator shall, after consultation with other interested Federal agencies, establish procedures and regulations for the disposal or storage of packages and containers of pesticides and for disposal or storage of excess amounts of such pesticides, and accept at convenient locations for safe disposal a pesticide the registration of which is [canceled under section 6(c)] *suspended under section 6(c) and canceled* if requested by the owner of the pesticides.

* * * * * * *

(d) CONTAINER DESIGN.—

(1) PROCEDURES.—

(A) Not later than 3 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.

(B) The regulations shall assure, to the fullest extent practicable, that the containers—

(i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers;

(ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from the containers;

(iii) facilitate the safe disposal of the containers; and

(iv) facilitate the safe refill and reuse of the containers.

(2) COMPLIANCE.—The Administrator shall require compliance with the regulations referred to in paragraph (1) not later than 5 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

(e) PESTICIDE RESIDUE REMOVAL.—

(1) PROCEDURES.—

(A) Not later than 3 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.

(B) The regulations may—

(i) specify, for each major type of pesticide container, procedures and standards providing for, at a mimimum, triple rinsing or the equivalent degree of pesticide removal;

(ii) specify procedures that can be implemented promptly and easily in various circumstances and conditions;

(iii) provide for reuse, whenever practicable, or disposal of rinse water and residue; and

(iv) be coordinated with requirements for the rinsing of containers imposed under the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.).

(2) COMPLIANCE.—Effective beginning 5 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendment of 1986, a State may not exercise primary enforcement responsible under section 26, or certify an applicator under section 11, unless the Administrator determines that the State is carrying out an adequate program to assure compliance with this subsection.

(f) PESTICIDE CONTAINER STUDY.—

(1) STUDY.—

(A) The Administrator shall conduct a study of options to encourage or require—

(i) the return, refill, and reuse of pesticide containers;

(ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and

(iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

(B) In conducting the study, the Administrator shall—

(i) consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations; and

(ii) assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures or actions.

(2) REPORT.—Not later than 2 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall submit to Congress a report describing the results of the study required under paragraph (1).

* * * * * * *

SEC. 21. SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

(a) *SECRETARY OF AGRICULTURE.*—The Administrator, before publishing regulations under this Act, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 25(a).

(b) *VIEWS.*—In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at his descretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as he deems proper.

(c) *Notice.*—In connection with all public hearings under this Act the Administrator shall publish timely notice of such hearings in the Federal Register.

SEC. 22. DELEGATION AND COOPERATION.

(a) * * *

* * * * * * *

(c) Effect on Certain Other Laws.—

(1) In general.—In exercising any authority under this Act, the Administrator shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be considered to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that such exercise of authority by the Administrator under this Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970.

(2) Coordination.—To ensure the safety and health of workers, the Administrator and the Secretary of Labor shall seek to reach such agreements and to coordinate the exercise of their statutory authority.

SEC. 23. STATE COOPERATION, AID, AND TRAINING.

[(a) Cooperative Agreements.—The Administrator may enter into cooperative agreements with States and Indian tribes—

[(1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this act through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this Act and to assist States and Indian tribes in implementing cooperative enforcement programs through grants-in-aid; and

[(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agreements, to train and certify applicators consistent with the standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.]

(a) Cooperative Agreements.—

(1) Purposes.—The Administrator may enter into cooperative agreements with States and Indian Tribes for the following:

(A) To delegate to any State or Indian Tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State

or Indian Tribe to cooperate in the enforcement of this Act, and to assist States and Indian Tribes in implementing cooperative enforcement programs through grants.

(B) To provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as agreed under such cooperative agreements, of conducting training programs for certification of applicators. Funds shall be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator.

(C) To provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under such cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State plan of each State approved under section 11(a)(2). Funds shall be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

(2) AUTHORIZATION FOR APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under this subsection.

* * * * * * *

SEC. 24. AUTHORITY OF STATES.

[(a) A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.]

(a) STATE REGULATION.—

(1) IN GENERAL.—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

(2) HOUSE OR GARDEN PESTICIDES.—

(A) This paragraph shall apply to any house or garden pesticide where—

(i) the pesticide is a formulated end-use product;

(ii) the pesticide has been registered under section 3(c)(5), or reregistered under section 4, after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986;

(iii) the Administrator has determined that the product as so registered or reregistered poses no significant toxicological concern; and

(iv) the Administrator has published the determination of no significant toxicological concern in the Federal Register.

(B) Except as provided in subparagraph (C), a State may not prohibit any sale or use permitted under this Act of a pesticide described in subparagraph (A) for which an application for State registration has been filed unless and until the State has finally acted on such application pursuant to applicable State law.

(C) This paragraph shall not preclude a State from prohibiting the sale or use of a pesticide if the State requires in the State registration process additional toxicity data beyond that required by the Administrator.

(b) *Uniformity.*—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

[(c)(1) A**]**

(c) Additional Uses.—

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within the State to meet special local needs in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State. *Such registration shall expire and be of no further effect, without further action by the Administrator—*

(A) at the end of the period, if any, provided as the duration of the registration by the State that approved it; or

(B) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide. *The Administrator shall establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use.*

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act that permits the residues of the pesticide on the food or feed. if the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 25 of this Act, that a State is not capable of exercising adequate controls to assure that State registration under this station will be in accord with

the purposes of this act or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

(d) DIFFERENCES IN USAGE AND RISK.—In promulgating any regulations or policies pertaining to the sale or use of pesticides within a State, the State shall take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

(e) UNIFORM TOLERANCES.—

(1) IN GENERAL.—

(A) Except as provided in paragraphs (2) and (3), no State or political subdivision thereof may, directly or indirectly, establish or enforce any regulatory limit on residues of a pesticide chemical in or on food that is not identical to a permissible residue level established under a Federal law, regulation, or enforcement requirement, if the residues result from use of a pesticide the initial registration or reregistration of which was approved—

(i) under section 3(c)(5) on or after April 25, 1985; or

(ii) on the basis of data determined by the Administrator to meet the requirements of part 158 of subchapter E of chapter I of title 40, Code of Federal Regulations.

(B)(i) Notwithstanding any other provision of this section, no requirement imposed by a State shall apply to a pesticide residue in or on food that complies with Federal and all applicable State laws at the time of pesticide use.

(ii) The Administrator, in consultation with the Secretary of Agriculture, shall consider feasible actions to minimize the duration of distribution of existing stocks of food that contain pesticide residues that comply with Federal and all applicable State laws at the time of pesticide use but that fail to comply with a new State regulatory limit.

(iii) The Administrator, in consultation with the Secretary of Agriculture, shall determine on an annual basis if feasible actions have been taken to minimize the duration of distribution of such stocks of food.

(2) EXEMPTIONS.—

(A) On petition of a State, the Administrator shall, by regulation promulgated after notice and opportunity for public hearing, exempt from paragraph (1), a State regulatory requirement if such requirement—

(i) is justified by compelling local conditions;

(ii) will not unduly burden interstate commerce; and

(iii) will not cause any food to be in violation of Federal law.

(B) The Administrator shall, after receiving comment from the Scientific Advisory Panel established under sec-

tion 25(d), respond to any State petition filed under this subsection within 60 days. If the Administrator fails to respond within 60 days, the State may establish and enforce the regulatory requirement contained in the petition until the Administrator responds to the petition.

(3) Imminent hazards.—Notwithstanding paragraphs (1) and (2), a State may, after notice and opportunity for public hearing, establish and enforce within its own jurisdiction a regulatory requirement regarding residues of a pesticide chemical in or on food if the State demonstrates that such requirement is necessary to prevent an imminent hazard of a substantial risk of serious harm to human health during the period required to obtain a response from the Administrator to a petition submitted under paragraph (2). A State must submit a petition under paragraph (2) within 10 days after the State promulgates a requirement under this subsection.

(4) Declaratory judgments.—A person may seek a declaratory judgment under section 2201 of title 28, United States Code, with respect to any requirement established by a State under this subsection on the ground that such requirement does not meet the standards established in this subsection. The State shall bear the burden of proof in any such action.

(5) Termination date.—This subsection shall cease to be effective after September 30, 1991.

SEC. 25. AUTHORITY OF ADMINISTRATOR.

[(a)(1) Regulations.—The**]**

(a) In General.—

(1) Regulations.—The Administrator is authorize in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

(2) Procedure.—

(A) **[Proposed regulations.—]** At least 60 days prior to signing any proposed regulations for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

(B) **[Final regulations.—]** At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement.

In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) **[**Time requirements.—**]** The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) **[**Publication in the federal register.—**]** The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

* * * * * * *

(3) Congressional committees.—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, he shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, *Nutrition,* and Forestry of the Senate.

[(4) Rule and regulation review.—

[(A) Congressional review.—Nothwithstanding any other provision of this Act, simultaneously with promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. Except as provided in subparagraph (B), the rule or regulation shall not become effective, if within 90 calendar days of continuous session of Congress after the date of promulgation, both Houses of Congress adopt a concurrent resolution, the matter after the resolving clause of which is as follows: "The Congress disapproves the rule or regulation promulgated by the Administrator of the Environmental Protection Agency dealing with the matter of   , which rule or regulation was transmitted to Congress on   ," the blank spaces therein being appropriately filled.

[(B) EFFECTIVE DATE.—If at the end of 60 calendar days of continuous session of Congress after the date of promulgation of a rule or regulation, no committee of either House of Congress has reported or been discharged from further consideration of a concurrent resolution disapproving the rule or regulation, and neither House has adopted such a resolution, the rule or regulation may go into effect immediately. If, within such 60 calendar days, such a committee has reported or been discharged from further consideration of such a resolution, or either House has adopted such a resolution, the rule or regulation may go into effect not sooner than 90 calendar days of continuous session of Congress after its promulgation unless disapproved as provided in subparagraph (A).

[(C) For the purposes of subparagraphs (A) and (B) of this paragraph—

[(i) continuity of session is broken only by an adjournment of Congress sine die; and

[(ii) the days on which either House is not in session because of an adjournment of more than 3 days to a day certain are excluded in the computation of 60 and 90 calendar days of continuous session of Congress.

[(D) EFFECT OF CONGRESSIONAL INACTION.—Congressional inaction on or rejection of a resolution of dispproval shall not be deemed an expression of approval of such rule.

[(E) JUDICIAL REVIEW.—

[(i) Any interested party, including any person who participated in the rulemaking involved, may institute such actions in the appropriate district court of the United States, including actions for declaratory judgment, as may be appropriate to construe the constitutionality of any provision of this paragraph. The district court immediately shall certify all questions of the constitutionality of this paragraph to the United States court of appeals for the circuit involved, which shall hear the matter sitting en banc.

[(ii) Notwithstanding any other provision of law, any decision on a matter certified under clause (i) of this subparagraph shall be reviewable by appeal directly to the Supreme Court of the United States. Such appeal shall be brought not later than 20 days after the decision of the court of appeals.]

(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

* * * * * * *

(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing *or by regulation,* is authorized—

(1)* * *

* * * * * * *

(5) to [prescribe regulations requiring] *require* any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and

* * * * * * *

(d) SCIENTIFIC ADVISORY PANEL.—[The] *Except with respect to a referral under section 3(c)(8)(F), the* Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall *be permanent and* consist of [7] *9* members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatifactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as he deems necessary, and he shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect in receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. [The advisory panel established under this subsection shall terminate September 30, 1987.] In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

(e) PEER REVIEW.—The Administrator shall, by written procedures, for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide [: Provided, That whenever]. *Whenever* the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriation disciplines.

(f) WORKER HEALTH AND SAFETY.—

(1) IN GENERAL.—

(A) The Administrator, as soon as practicable after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, shall promulgate regulations that require the protection, as appropriate and necessary, of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas.

(B) The Administrator shall promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement that may be established by the Administrator under this subparagraph shall not apply to any person who is required to receive the training described in subsection (d) or (e) of section 11.

(C) For purposes of subparagraphs (A) and (B), the term 'employees' does not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

(2) RULEMAKING PROCEDURES.—

(A) The Administrator shall promulgate regulations under paragraph (1) for employees not described in subparagraph (B) not later than 3 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

(B) The Administrator shall provide a period of at least 6 months for comments on proposed regulations issued under paragraph (1) that apply to agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas. Such regulations shall be promulgated not later than 2 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

(3) REPORT ON REGULATIONS.—Not later than 6 months after the date of the publication of the notice of proposed rulemaking issued for the regulations for employees described in paragraph (2)(B) to be promulgated under paragraph (1), the Secretary of Agriculture shall submit to the Administrator a report on the impact, cost, and effectiveness of such regulations on the agricultural community. The Secretary shall submit a copy of such report to Congress.

(4) COPY OF REGULATIONS.—Simultaneously with the promulgation of regulations under paragraph (1), the Administrator shall transmit a copy of such regulations to the Secretary of the Senate and the Clerk of the House of Representatives. Such regulations may not become effective until the expiration of 120 days after the date such regulations are so transmitted.

SEC. 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

(a) *In General.*—For purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

(1) has adopted adequate pesticide use laws and regulations [; *Provided,* That], *except that* the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

* * * * * * *

(b) *Special Rules.*—Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section [4] *11* of this Act in effect on the date of enactment of the Federal Pesticide Act of 1978 not later than six months after that date.

(c) *Administrator.*—The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. [Notwithstanding the provisions of section 2(e)(1) of this Act] *Notwithstanding section 2(kk),* during any period when the Administrator has such enforcement responsibility, section [8(b) of this Act] *9* shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section [9(a) of this Act] *9* shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

(d) Expiration.—Notwithstanding subsections (a) and (b), the primary enforcement responsibility of a State under this section for pesticide use violations shall expire on January 1, 1990, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in section 14.

SEC. 27. FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS.

(a) *Referral.*—Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. [If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this Act.] *If a State—*

(1) does not promptly initiate appropriate investigative action after receiving such referral; or

(2) does not initiate appropriate enforcement action within 90 days after receipt of such referral,

the Administrator may act on such complaint or information in accordance with this Act.

(b) *Notice.*—Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) *Construction.*—Neither section 26 of this Act not this section shall limit the authority of the Administrator to enforce this Act, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

* * * * * * *

[SEC. 31.] [*SEC. 32.* AUTHORIZATION FOR APPROPRIATIONS.]

[There is authorized to be appropriated such sums as may be necessary to carry out the provisions of this Act for each of the fiscal years ending June 30, 1973, June 30, 1974, and June 30, 1975. The amounts authorized to be appropriated for any fiscal year ending after June 30, 1975, shall be the sums hereafter provided by law.

[There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1975, and ending September 30, 1976, the sum of $47,868,000 and for the period beginning October 1, 1976, and ending September 30, 1977, the sum of $46,636,000, and for the period beginning October 1, 1977, and ending September 30, 1978, the sum of $54,500,000, and for the period beginning October 1, 1978, and ending September 30, 1979, such sums as may be necessary, but not in excess of $70,000,000.]

SEC. 31. PROTECTION OF GROUND WATER.

(a) Notification.—

(1) Requirement.—When a registrant of a pesticide obtains reliable analytical data that a pesticide has been detected at any ground water sampling point, the registrant shall file a report containing such information within 15 working days with the Administrator, the Governor in each State where such pesticide has been detected, and the owner of the property at the ground water sampling point if known.

(2) Content of report.—A report required under paragraph (1) for detection of a pesticide shall contain information known to the registrant on the level of detection, frequency of detection,

location (including depth), date, well construction, soil type, and analytical method used, including information on the precision, accuracy, and limit of detection of the method, and any quality assurance and control procedures.

(b) REVIEW FOR FURTHER ACTION.—On receiving information of a detection of a pesticide at any ground water sampling point, the Administrator shall promptly review the reported information to determine the reliability of the detection and to determine whether further action should be taken to protect ground water.

(c) MONITORING.—

(1) REQUIREMENT FOR MONITORING.—

(A) If the Administrator determines that additional data on the presence of the pesticide in ground water are required to maintain in effect an existing registration of the pesticide, the Administrator may, under section 3(c)(2)(B), require registrants of the pesticide to conduct ground water monitoring.

(B) The Administrator shall consult with the Secretary of Agriculture, the heads of other appropriate Federal agencies, and Governors concerning the design and scope of monitoring rerequirements imposed under this paragraph. The design and the scope of the monitoring requirement should take into account information such as the magnitude and frequency of the detection, pattern of pesticide use and soil types involved in the detection, physical, and chemical properties of the pesticide, rainfall patterns, well construction, rates of degradation, reliability and analytical accuracy of the detection, and results of State or other sponsored monitoring.

(C) To the extent feasible, monitoring should be conducted at representative geographical and hydrogeological areas associated with locations and conditions of concern as determined by the Administrator.

(2) JUDICIAL REVIEW.—Monitoring requirements imposed under this subsection shall be subject to judicial review under section 16.

(d) GROUND WATER RESIDUE GUIDANCE LEVELS.—

(1) REQUIREMENT.—

(A) The Administrator, on the Administrator's own initiative, may issue a ground water residue guidance level for a pesticide.

(B) The Administrator shall issue a ground water residue guidance level for a pesticide whenever the Administrator registers or reregisters a pesticide if the Administrator determines that the pesticide has the potential to leach into ground water.

(C) In addition, the Administrator shall issue a ground water residue guidance level for a pesticide if—

(i) based on reliable analytical data, the pesticide has been detected at ground water sampling points in 3 different geographical areas;

(ii) based on reliable analytical data, the pesticide has been detected in a drinking water well or well field that serves a population of over 10,000 people; or

(iii) the head of a Federal agency or a Governor petitions the Administrator to set a ground water residue guidance level for the pesticide.

(2) STANDARDS FOR DETERMINING GROUND WATER RESIDUE GUIDANCE LEVELS.—

(A) If the Administrator has promulgated a maximum contaminant level under section 1412(b)(3) of the Public Health Service Act (42 U.S.C. 300g-1(b)(3)), the ground water residue guidance level shall be set at the maximum contaminant level within 30 days of being required under paragraph (1).

(B)(i) If a maximum contaminant level has not been promulgated, the Administrator, in the Administrator's discretion, may use a health advisory level established under the Public Health Service Act (42 U.S.C. 201 et seq.) in establishing a ground water residue guidance level.

(ii) The Administrator shall consider the level of the pesticide in drinking water at which no known or anticipated adverse effects on the health of persons occur, the need for an adequate margin of safety, the nature of the toxic effects caused by the pesticide, and the validity, completeness, and adequacy of data about the pesticide.

(iii) If all required chronic, oncogenicity, reproduction, or teratogenicity data are absent or invalid for the pesticide, the ground water residue guidance level for the pesticide shall be at the limit of detection.

(iv) If any required chronic, oncogenicity, reproduction, or teratogenicity data are absent or invalid for the pesticide, the ground water residue guidance level for the pesticide shall include an additional margin of safety that takes into account the absence of such data.

(3) PROCEDURES.—

(A) If the Administrator is required under paragraph (1) to issue a ground water residue guidance level for a pesticide and the ground water residue guidance level is issued pursuant to paragraph (2)(B), the Administrator shall issue an interim ground water residue level within 30 days after the requirement takes effect. Before issuing a final ground water residue guidance level for a pesticide, the Administrator shall publish an interim ground water residue guidance level for the pesticide in the Federal Register and allow public comment for at least 30 days.

(B) The issuance or revision of interim ground water residue guidance levels and proposals to revise ground water residue guidance levels shall not be required to comply with the procedural requirements imposed by subparagraphs (A) and (B) of section 25(a)(2) or by section 25(a)(3), 25(a)(4), or 25(d). During the public comment period, the Administrator shall invite comment on the level from the Secretary of Agriculture, the Scientific Advisory Panel established under section 25(d), and the congressional committees designated in section 25(a)(3).

(C) Within 3 months after issuing an interim ground water residue level, the Administrator shall issue a ground water residue guidance level. Until a final ground water residue guidance level is issued under paragraph (1) for a pesticide, an inteim ground water residue guidance level issued for the pesticide shall remain in effect.

(4) REVISION OF GROUND WATER RESIDUE GUIDANCE LEVELS.—The Administrator may revise a ground water residue guidance level for a pesticide. The Administrator shall allow at least 30 days for public comment on any proposed revision.

(5) JUDICIAL REVIEW.—An interim ground water residue guidance level shall not be subject to judicial review before the expiration of 3 months after its issuance. Judicial review of any final ground water residue guidance level to establish an interim or final ground water residue guidance level shall be governed by section 16. A ground water residue guidance level established under paragraph (2)(A) shall not be subject to judicial review under this Act.

(e) SITE-SPECIFIC RESPONSE.—

(1) REQUIREMENT.—

(A) If the Administrator determines that a pesticide is present in a drinking water well at a concentration that exceeds the final ground water residue guidance level and that the presence of the pesticide in the drinking water well may be the result of use of the pesticide in accordance with the labeling on the pesticide or as a result of widespread and commonly recognized practice involving the pesticide, the Administrator shall—

(i) notify the Governor of the determination of the Administrator; and

(ii) provide the Governor, subject to section 10(h), with all information relevant to the determination.

(B) The Governor of the State shall take appropriate action within 90 days of such notification to bring and retain the concentration of the pesticide at such drinking water well at or below the ground water residue guidance level or to prevent consumption of drinking water exceeding such level.

(2) PROCEDURES.—

(A) After January 1, 1989, if—

(i) a State does not have the authority or fails to exercise the authority of the State to insure that the State complies with paragraph (1);

(ii) a pesticide is present in a drinking water well in the State at a concentration that exceeds the final ground water residue guidance level; and

(iii) the presence of the pesticide may be the result of use in accordance with the labeling or of widespread and commonly recognized practice,

the Administrator shall issue an order prohibiting use of the pesticide in the vicinity of the drinking water well or taking such other site specific actions under this Act, as the Administrator considers necessary, to meet the requirements of paragraph (1) with respect to such drinking water well.

(B) The Administrator shall publish notice of the proposed order in the Federal Register and take appropriate steps to inform all registrants, potentially affected persons, and interested members of the public. Such notice shall specify the factual findings and conclusions relied on in support of the decision.

(C) A person adversely affected by an order, action, or failure to act under this paragraph (1) shall have an opportunity for an expedited hearing, pursuant to the procedures in section 6(c)(2), to determine whether the Administrator has met the requirements of this paragraph.

(D) Notwithstanding any other provision of this Act, a hearing shall be held and a determination made under this subsection within 75 days after receipt of a request for such a hearing.

(E) The Administrator shall provide reasonable procedures for a petition to modify or terminate the action of the Administrator under this paragraph if the concentration of the pesticide in the water from the drinking water well no longer exceeds the applicable ground water residue level and will likely remain below such level.

(3) JUDICIAL REVIEW.—Judicial review of actions taken under this subsection shall be governed by section 16.

(f) REGISTRATION AMENDMENTS.—

(1) REQUIREMENT.—

(A)(i) After reviewing reliable analytical data, the Administrator shall determine whether there is a reasonable likelihood that the ground water residue guidance level for a pesticide will be exceeded in drinking water wells in different localities.

(ii) If the Administrator makes a determination that there is a reasonable likelihood of exceeding such level in different localities, the Administrator shall promptly require amendments to the registration of the pesticide involved that are reasonably necessary to ensure that the use of the pesticide in accordance with the amended registration will not cause the final ground water residue guidance level to be exceeded in drinking water wells.

(iii) The Administrator shall make such determination public.

(iv) If the Administrator proposed to require registration amendments under this paragraph, the Administrator shall notify registrants of such amendments and shall publish notice of the decision in the Federal Register. Such notice shall include the determination of the Administrator whether the presence of the pesticide in drinking water wells appears to have been the result of use of the pesticide in accordance with the labeling or widespread and generally recognized practice.

(B)(i) After reviewing reliable analytical data, the Administrator shall determine whether there is a reasonable likelihood that the ground water residue guidance level for a pesticide will be exceeded in potential drinking water in different localities.

(ii) If the Administrator makes a determination that there is a reasonable likelihood that such level will be exceeded in different localities, the Administrator shall promptly require amendments to the registration of a pesticide involved that are reasonably necessary to ensure that use of the pesticide in accordance with the amended registration will not cause the final ground water residue guidance level to be exceeded in potential drinking water.

(iii) If the Administrator proposes to require amendments under this paragraph, the Administrator shall notify registrants of such amendments.

(iv) In establishing such amendments, the Administrator shall—

(I) meet the requirements of subparagraph (A);

(II) take into account information submitted by States on land or ground water use classification or other governmental actions that could affect when ground water may be used for drinking water; and

(III) consider the views of the Secretary of Agriculture, other heads of appropriate Federal agencies, and Governors as required in paragraph (2).

(2) CONSULTATION.—

(A) In taking action under paragraph (1), the Administrator shall consult with the Secretary of Agriculture and the Governor in each State where the pesticide involved has been detected in any ground water sampling point and each other State in which there is a significant use of the pesticide.

(B) The Administrator shall notify the Governor of the determination of the Administrator that there is a reasonable likelihood that the ground water residue guidance level will be exceeded and shall provide the Governor with all information relevant to this determination subject to section 10(h).

(C) States shall promptly provide the Administrator within information relevant to taking action under this section and shall make recommendations regarding necessary registration amendments with respect to the State.

(3) SCOPE OF AMENDMENTS.—

(A) Amendments to the registration of a pesticide may include—

(i) limitations on the purposes for and location at which the pesticide may be used, considering factors such as environmentally sensitive areas and conditions;

(ii) limitations on the rate at which the pesticide is applied;

(iii) limitations on the time or frequency of pesticide use;

(iv) limitations on the method of pesticide application, storage, handling, or disposal;

(v) reporting or other requirements, including label changes or changes in classification;

(vi) requirements for the training or certifications of pesticide applicators or other persons using the pesticide;

(vii) required site specific responses; or

(viii) any other requirement under this Act to ensure that the application ground water residue guidance level will not be exceeded.

(B) The amendments to the registration of a pesticide shall, to the extent feasible, be directed to the same or similar use of pesticide, geographical and hydrogeological areas and other conditions that led to the determination under subparagraph (A) or (B) of paragraph (1).

(C) In taking regulatory action under this subsection, the Administrator may utilize recommendations provided by States under paragraph (2).

(D) In requiring such amendments, the Administrator shall consider the effect of any voluntary actions by registrants or other persons, including actions by the State to prevent the ground water residue guidance level from being exceeded, and compliance with other environmental laws.

(4) PROCEDURES.—Registration amendments shall be imposed in accordance with the procedures required by this Act.

(g) INFORMATION ON PESTICIDES IN GROUND WATER.—The Administrator may collect and make available through a public information file information concerning the detection of pesticides in any ground water sampling point. The file may summarize for each pesticide that has been detected in ground water, based on reliable analytical data, whether the pesticide has been detected at a concentration that exceeds the applicable ground water residue guidance level and whether the presence of the pesticide in ground water appears to have been caused by use of the pesticide in compliance with this Act.

(h) TECHNICAL ASSISTANCE TO STATES.—The Administrator shall provide technical information to a Governor of a State to assist in implementing this section. Subject to section 10(h), the technical information shall include data on the toxicity, environmental fate, physical or chemical pesticide ingredient characteristics, predictive modeling, exposure and other relevant subjects. In addition, the Administrator shall provide information, to the extent reasonably available, on the alternative methods of pest control and on agricultural or other management practices that could minimize the presence of pesticides in ground water.

(i) SPECIAL REVIEW.—On receiving reliable analytical data that a pesticide has been detected above the ground water residue guidance level not in a drinking water well or potential drinking water, the Administrator may initiate a public interim administrative review under section 3(c)(8) to determine whether the pesticide may cause unreasonable adverse effects on the environment from such use.

(j) EFFECT ON OTHER PROVISIONS.—Nothing in this section shall limit the authority of the Administrator or of any State under other provisions of this Act or under any other law.

SEC. 32. AUTHORIZATION FOR APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act (other than sections 23(a) and 31)—

(1) $78,363,500 for fiscal year 1987, of which not more than $13,735,500 shall be available for research under this Act;

(2) $87,414,200 for fiscal year 1988, of which not more than $14,343,600 shall be available for research under this Act;

(3) $91,673,400 for fiscal year 1989, of which not more than $14,978,200 shall be available for research under this Act;

(4) $98,305,800 for fiscal year 1990, of which not more than $15,625,900 shall be available for research under this Act; and

(5) $106,808,700 for fiscal year 1991, of which not more than $16,300,100 shall be available for research under this Act.

TITLE 35, UNITED STATES CODE

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Sec.
151. Issue of patent.

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158. Restoration of patent term for certain agricultural and chemical products.

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§ 158. Restoration of patent term for certain agricultural and chemical products

(a)(1) The term of a patent that claims a product subject to a regulatory review period or a method for using such a product or a method for manufacturing such a product shall be extended, in accordance with this section, from the original expiration date of the patent if—

(A) the product sponsor notifies the Commissioner in compliance with the provisions of subsection (g)(1);

(B) the product has been subject to a regulatory review period pursuant to statute before its commercial marketing or use;

(C) the term of the patent has never been extended; and

(D) the patent to be extended has not expired prior to notice to the Commissioner under subsection (b)(1).

(2) The rights derived from any claim of any patent extended under paragraph (1) shall be limited in scope during the period of any extension as follows:

(A) In the case of any patent, to the scope of such claim that relates to the product subject to regulatory review.

(B) With respect to a product that is a chemical substance for which notice is required under section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) or that is a mixture that contains a substance for which such notice is required and—

(i) that is subject to a rule requiring testing under section 4(a) of such Act (15 U.S.C. 2603), the term means a period commencing on the date the product sponsor has initiated the testing required in such rule and ending on the expiration of the notice period for such chemical substance or mixture under section 5 of such Act, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the

date on which such order or injunction is dissolved or set aside; or

(ii) that is not subject to a testing rule under section 4 of such Act, the term means a period commencing on the earlier of the date the product sponsor—

(I) submits, in accordance with regulations issued by the Administrator, a notice under section 5 of such Act, or

(II) initiates a major health or environmental effects test on such chemical substance or mixture,

and ending on the expiration of the notice period for such substance under section 5 of such Act or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside.

No regulatory review period shall be deemed to have commenced until a patent has been granted for the product that is subject to regulatory review, for the method for using such product, or for the method for producing such product.".

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§ 271. Infringement of patent

(a) * * *

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(g)(1) Except as provided in paragraph (2), during the last 2 years of the term of a patent relating to a pesticide (including a patent that claims the pesticide, a method for using the pesticide, or a method for manufacturing the pesticide) that is or has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), or that is marketed with the permission of the patent holder, it shall not be an act of infringement of the patent—

(B) In the case of a patent that claims a method of manufacturing a product, to the method of manufacturing as used to make the approved product.

(3)(A) Subject to subparagraph (B), the term of a patent shall be extended by the time equal to the regulatory review period that occurred after such patent was granted.

(B)(i) In determining a regulatory review period for purposes of subparagraph (A), if an application or notice described in paragraph (4)(B)(ii) or (4)(C)(ii) of subsection (c) was rejected and returned to the product sponsor because of insufficiency of data, the period beginning on the date the application was rejected for insufficiency of data and ending on the date the application was subsequently accepted shall be excluded, except that if during such period the product sponsor conducts a major health or environmental effects test, the period during which such test is conducted shall not be excluded.

(ii) In determining a regulatory review period for purposes of subparagraph (A), the regulatory review period shall be reduced by any period determined under subsection (b)(2) during which the product sponsor did not act with due diligence.

(iii) In no event shall the term of any patent be extended for more than five years. No term of any extended patent may exceed twenty-five years from the date of filing of the earliest United States patent application that provides support under section 120 of this title for any claim of the patent to be extended. If the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had not ended, it shall be measured from the date of enactment and the period of extension for the patent shall not exceed three years. If the regulatory review period for a product began before the date of enactment of this section, and if on such date the regulatory review period has been completed, there shall be no extension of the patent.

(C) In no event shall more than one patent be extended for the same regulatory review period for any product.

(D) For purposes of the extension of the term of a patent relating to a pesticide under subsection (a)—

(i) each formulation of the pesticide containing the identical active ingredient shall be considered the same pesticide; and

(ii) no pesticide may be the subject of more than one patent extension.

(b)(1) To obtain an extension of the term of a patent under subsection (a), the product sponsor shall notify the Commissioner within sixty days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. If the product sponsor is not the owner of record of the patent, the notification shall include the written consent of the owner of record of the patent. Such notification shall be in writing and shall—

(A) identify the Federal statute under which regulatory review occurred;

(B) state the dates on which the regulatory review period commenced and ended;

(C) identify the product for which regulatory review was required;

(D) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(1)(B) occurred have been satisfied and commercial marketing or use of the product is not prohibited under the Federal statute identified in subparagraph (A);

(E) identify the patent and any claim thereof to which the extension is applicable; identify the filing date of the earliest United States application referred to in subsection (a)(3)(B)(iii); and state that the term of the patent has never been extended and that no other patent has been extended for the regulatory review period for the product; and

(F) include such other information as the Commissioner may require.

(2)(A) Within 60 days after the submittal of the extension notification under paragraph (1), the Commissioner shall notify the Administrator if the patent claims a pesticide subject to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), a chemical substance or mixture subject to the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), or a method of using or manufacturing such a pesticide, substance, or mixture, of the extension notification

and shall submit to the Administrator a copy of the extension notification. Not later than thirty days after the receipt of the extension notification from the Commissioner, the Administrator shall review the dates contained therein pursuant to paragraph (1)(B) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(B) If a petition is submitted to the Administrator, not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the product sponsor did not act with due diligence during the applicable regulatory review period, the Administrator shall, in accordance with regulations promulgated by the Administrator, determine if the product sponsor acted with due diligence during the applicable regulatory review period. The Administrator shall make such determination not later than 90 days after the receipt of such a petition. The Administrator may not delegate such authority to an office below the Assistant Administrator for Pesticides and Toxic Substances.

(C) The Administrator making a determination under subparagraph (B) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination, together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Administrator to hold a hearing on the determination. Such a hearing shall be an informal hearing that is not subject to section 554, 556, or 557 of title 5, United States Code. If such a request is made within such period, the Administrator shall hold such hearing not later than thirty days after date of the request, or at the request of the person making the request, not later than sixty days after such date. The Administrator shall provide notice of the hearing to the product sponsor and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Administrator shall affirm or revise the determination that was the subject of the hearing and notify the Commissioner of such affirmation or any revision of the determination and shall publish such affirmation or revision in the Federal Register.

(D) Failure of a product sponsor to act with due diligence during a regulatory review period shall not be a defense in any action involving the infringement of a patent.

(E) For purposes of this paragraph, the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(F) In a proceeding under this paragraph, the Administrator may take into consideratioin the failure of a product sponsor to submit data that the product sponsor knew or reasonably should have known was necessary to support an application or notice described in paragraph (4) of subsection (c).

(G) The Administrator and the Commissioner may establish such fees as are appropriate to cover the costs of carrying out their respective duties and functions under this section.

(3)(A) The Commissioner shall determine that a patent is eligible for extension under subsection (a) and that the requirements of subsection (b)(1) have been complied with. A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the notification under subsection (b)(1). If the Commissioner determines that the patent is eligible for extension, and upon receipt of a final determination of the applicable regulatory review period under paragraph (2), he shall issue to the owner of record of the patent a certificate of extension, under seal, stating the length of the extension, identifying the product and the statute under which regulatory review occured, and specifying any claim to which such extension is applicable. Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent. The Commissioner shall publish in the Official Gazette of the Patent and Trademark Office a notice of such extension.

(B) If the term of a patent for which notificaiton has been submitted under subsection (b)(1) would expire before a certificate of extension is issued or denied under subparagraph (A) respecting the notification, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(4) If information submitted by a product sponsor during a regulatory review period is considered a trade secret or confidential commerical or financial information under the law under which such regulatory review occurred, such information may only be disclosed under this section in accordance with such law, except that the Administrator may disclose information to the extent necessary to publish a notice and hold a hearing under paragraph (2).

(c) As used in this section:

(1) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) The term "product" means any machine, manufacture, or composition of matter for which a patent may be obtained and is limited to—

(A) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act (15 U.S.C. 2601 et seq.); or

(B) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

(3) The term "major health or environmental effects test" means an experiment or study to determine or evaluate health or environmental effects that requires at least six months to conduct, not including any period for analysis or conclusions, and the data from which is submitted to receive permission for commercial marketing or use.

(4) The term "product sponsor" means any person who, with the consent of the patent owner, initiates testing or investigations, claims an exemption, or submits an application, petition, protocol, request, or notice described in paragraph (5) of this subsection.

(5) The term "regulatory review period" has the following meaning:

(A) With respect to a product that is a pesticide, the term means the sum of—

(i) the period beginning on the earlier of the date the product sponsor (I) initiates a major health or environmental effects test on such pesticide, or (II) requests, in accordance with regulations issued by the Administrator, the grant of an experimental use permit for the pesticide under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c), and ending on the date an application is submitted for registration of such pesticide pursuant to section 3 of such Act (7 U.S.C. 136a); and

(ii) the period beginning on the date an application is submitted, in accordance with regulations issued by the Administrator, for registration of such pesticide pursuant to section 3 of such Act and ending on the date such pesticide is first registered, either conditionally or fully, under such section.

(A) to make, use, or sell the pesticide solely for testing reasonably related to the development and submission of data to comply with such Act; or

(B) to obtain a tolerance, exemption from the need for a tolerance, or food additive regulation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) If the patent of such a pesticide is extended under section 158 and the extension is for less than 2 years, the period during which such testing may occur without infringement shall begin 1 year before the patent expires.

(3) Paragraphs (1) and (2) shall apply only to the first patent the effect of which was to make an infringement the unlicensed manufacture, use, or sale of the patented product as a pesticide.

(4) It shall be an act of infringement for any person, other than the patent holder or the licensee of the patent, to submit an application for the registration under the Federal Insecticide, Fungicide, and Rodenticide Act of a pesticide covered by the first patent, as described in paragraph (3), before expiration of such patent.

(5) For purposes of this paragraph, each formulation of a pesticide containing the identical active ingredient shall be considered the same pesticide.

ACT OF AUGUST 4, 1965

AN ACT To facilitate the work of the DEPARTMENT OF AGRICULTURE, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * * * * * *

SEC. 2. (a) * * *

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(c) The Secretary of Agriculture is authorized to make grants, for periods not to exceed five years in duration—

(1) to land-grant colleges and universities, research foundations established by land-grant colleges and universities, State agricultural experiment stations, and to all colleges and uni-

versities having a demonstrable capacity in food and agricultural research, as determined by the Secretary to carry out research to facilitate or expand promising breakthroughs in areas of the food and agricultural sciences of importance to the Nation; and

(2) to State agricultural experiment stations, land-grant colleges and universities, research foundations established by land-grant colleges and universities, colleges and universities receiving funds under the Act of October 10, 1962 (16 U.S.C. 582a et seq.) and accredited schools or colleges of veterinary medicine, to facilitate or expand ongoing State-Federal food and agricultural research programs that (A) promote excellence in research, (B) promote the development of regional research centers, (C) promote the research partnership between the Department of Agriculture and such colleges and universities, such research foundations or State agricultural experiment stations, or (D) facilitate coordination and cooperation of research among States.

The Secretary in making grants under paragraph (2)(B) shall provide support for the interregional project number 4 program (commonly referred to as the "IR4 program"). No grant may be made under this subsection for any purpose for which a grant may be made under subsection (d) or for the planning, repairs, rehabilitation, acquisition, or construction of a building or facility. These grants shall be made without regard to matching funds. Four percent of the amount appropriated for any fiscal year to carry out this subsection may be retained by the Secretary to pay administrative costs incurred by the Secretary to carry out this subsection.

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ADDITIONAL VIEWS OF SENATORS PATRICK LEAHY AND TOM HARKIN

The Federal Insecticide, Fungicide, and Rodenticide Amendments Act of 1986 is one of the most important bills to be considered by the Senate Agriculture Committee in this Congress. A great deal of effort has been expended in the development of this bill, and there are many provisions of the bill that are major improvements to existing authorities.

However, certain provisions of the Committee-reported bill, if enacted without change, cannot be considered as major improvements to a statute that is designed to protect human health and the environment. In particular, the Committee adopted two provisions that we believe must be modified or deleted before the Senate passes the bill.

The first provision is an amendment to section 24 that establishes uniform pesticide tolerance levels. In essence, the amendment prohibits a State from establishing a pesticide residue tolerance level more restrictive than the federally established level. This amendment should be deleted from the bill.

The second provision is the addition of section 31, "Protection of ground water." The new ground water provisions could and should be modified to provide for better environmental protection.

UNIFORM TOLERANCES

During consideration of this bill by the Committee, a provision was adopted that restricts the ability of a State to limit pesticide contamination of food sold to its citizens. While this provision would be "sunset" under the Committee bill in 1991, we have serious reservations about the need, precedent, and the administrative problems involved.

The authority to protect the health and safety of citizens is one of a State's most fundamental powers. We do not believe that the Federal government should restrict the States' ability to provide such protection unless there is a compelling National reason for doing so. Marketing convenience simply is not sound reason to deprive the States of this basic right.

As with other areas of pesticide regulation, Federal tolerances should continue to be mandatory minimum standards with the States having the power to adopt stricter standards of protection for their citizens. States have long been able to set and enforce residue tolerances on food sold within their borders, and they have exercised this authority responsibly. State-established tolerances have been the exception rather than the rule. Stricter State standards have been established only with respect to two pesticides—ethylene dibromide (EDB) and daminozide.

In 1984, several States established separate tolerances for EDB, a soil fumigant and a fumigant for citrus, stored grain, and other food products. Such State actions were prompted by a lengthy delay in establishing a Federal tolerance level for EDB. EPA was unable to conclude its chaotic regulatory review of the pesticide's registration despite widespread findings of EDB residues in foods and in ground water. Without a binding legal standard for residues, States were left to their own to act until Federal law could catch up with the explosive situation. If anything, the EDB example indicates that potential action by a State may serve as a good prod for EPA, deterring sluggish reactions in the future.

This year, two States established seperate tolerances for daminozide, a growth regulator used primarily on apples and peanuts. Again, State actions have been prompted by delays at the Federal level in setting a safe tolerance level when evidence indicated one was needed. In September 1985, EPA announced plans to cancel registrations of daminozide because of data showing it to be a carcinogen. But in January 1986, the Agency reversed that decision and decided to ask for further data which will not be submitted until 1988. The States decided not to wait for the Federal government to obtain further data to quantify the health risk and acted to protect their citizens from exposure to this chemical.

The record of State tolerance-setting shows a clear pattern of responsible action. Nothing in the history of this issue suggests that a State has acted to willfully obstruct commerce. Rather, the actions have been taken in the light of clear risk when the Federal government has been unable, under Federal law, to take responsible action expeditiously.

Several groups, largely food manufacturers and distributors, support this prohibition on strict State-established pesticide residue tolerances because they believe that a patchwork of State regulations concerning food would make it difficult for national food companies to do business. We believe their fears to be unfounded. The banning of EDB and daminozide are the only examples of State action anyone can point to—and, under any circumstances, public health is a more important concern than possible, limited, temporary disruptions of interstate commerce.

It also should be noted that other environmental statutes provide for the Federal government to establish minimum standards that States may make more stringent. The Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act all allow States to impose more stringent requirement. Likewise, we believe that the States should continue to be allowed to establish stricter pesticide residue tolerances on food sold within their borders. As a practical matter, the public should not consider the EPA, or any other governmental agency, to be infallible, especially in the area of health and safety. The authority of the States to establish separate residue tolerances on food provides additional safeguards to the public.

The uniform tolerances provision adopted by the Committee is opposed by 92 chemical companies and 41 environmental, labor, and consumer groups. Deleting this provision during consideration of the bill on the Senate floor would be wise environmental policy.

GROUNDWATER

Groundwater pollution is a matter of grave concern. We all have a vital interest in having EPA do more to assure that public health is not jeopardized by exposure to pesticide-contaminated groundwater.

We are not convinced that the groundwater provision the Committee adopted will adquately address the serious and growing problem of pesticide contamination of our Nation's groundwater. The provision could be stronger and could better emphasis concern for protecting our water resources. Further, the Committee may inadvertently be doing a great disservice both to the Nation's present groundwater users and to future users if we hold out the promise of a Congressional response to this problem that falls short of what could and should be done.

First, it is imperative that the section not be read as a restriction on EPA's groundwater authorities. It is an expansion and addition to current authorities. The record must be absolutely clear on this point.

This section does not restict EPA authority under other provisions of this Act, but there are no other provisions in this Act which speak exclusively to groundwater. This section, on the other hand, is entitled "Groundwater Authority" and it includes, along with certain new mandates to the EPA Administrator, a restatement of existing monitoring authority. That combination could imply a consolidation of all groundwater authority into one section of FIFRA. Certainly, the Committee does not intend to restrict EPA authority.

Second, we believe that our national environmental policy must be established with a view to the Nation's long-term interests, and with a view toward *preventing* contamination of our water resources. Unfortunately, the groundwater section of the Committee-reported bill offers a groundwater policy that is based almost exclusively on response to contamination. Surely, we need to establish a policy that will ensure that safety hazards will not be ignored until a disaster strikes. We must not condone the contamination of groundwater. We must take all reasonable steps to prevent it.

Members of the Committee understand well the massive task EPA must accomplish in the area of pesticide regulation in the next few years. We suspect that few of us were surprised at the General Accounting Office's recent assessment of the Pesticide Office's resource needs. The bill will not bridge the gap between EPA funding needs and resources available. As a result, no matter how well we draft the section dealing with site-specific responses, the Agency cannot mount an effective effort against pesticide contamination of groundwater on a case-by-case response basis. To better protect underground sources of drinking water, EPA must use its authorities more effectively and when necessary amend pesticide registrations. In this area, the amendment is—despite considerable effort on the part of the drafters—still woefully inadequate.

We do not believe any Member of the Committee wants EPA to be in a position of waiting until there is "a reasonable likelihood" that drinking water standards will be exceeded in wells in several localities before EPA initiates proceedings to amend the registration of a leaching pesticide. Nor do we believe the Committee intends to establish a short-sighted policy that offers lesser protections to underground sources of drinking water that have not yet been tapped. Surely, we do not intend to condone contamination beyond drinking water standards simply because the contamination does not happen to intersect a drinking water well. Frankly, we fail to see the difference between that approach and the approach that the Agency has already stumbled into with Temik and EDB. EPA's past timidity is not as satisfactory model for new public policy.

EPA clearly needs to look ahead, to assess the pesticides that are leaching into groundwater, and to work with the manufacturers and the users of such pesticides to assure that the national label restrictions limit to the greatest extent practicable the contamination of underground sources of drinking water.

We believe that the registration amendment section of the reported bill should, and hopefully will, be interpreted by EPA so as to establish a regional but pro-active approach—responding to contamination of groundwater at levels of concern, but moving on registration amendments before drinking water sources that we use today to or that we may need tomorrow are in serious jeopardy. However, we are deeply concerned that the section might be interpreted otherwise, and we cannot support a Congressional "answer" that may be used as an excuse for inaction.

CONCLUSION

Years of effort on the part of several organizations concerned about safer uses of pesticides have been devoted to formulating a FIFRA bill this year. For example, many organizations supported S. 2215, which is the source of many of the major provisions of the Committee-reported bill. Those organizations include the Campaign on Pesticide Reform—a coalition of 41 consumer, environmental, and labor groups—and the National Agricultural Chemicals Association, whose membership includes some 92 companies.

In our judgment, the Senate must make necessary changes in the Committee-reported bill and pass legislation that strengthens—but not weakens—FIFRA.

Patrick Leahy.
Tom Harkin.

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